

# **EXHIBIT 53**

Page 1

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF NEW JERSEY  
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5           IN RE:   JOHNSON & JOHNSON           MDL NO.:  
6           TALCUM POWDER PRODUCTS           16-2738 (MAS)(RLS)  
7           MARKETING, SALES PRACTICES,  
8           AND PRODUCTS LIABILITY  
9           LITIGATION  
10          -----

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12                   EXPERT DEPOSITION OF  
13                   BERNARD L. HARLOW, PHD  
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15                   Tuesday, April 9, 2024  
16                   9:27 a.m. Eastern Time  
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23           Reported by:   Denise Dobner Vickery, CRR, RMR  
24           JOB NO.: 6474272

<p style="text-align: right;">Page 2</p> <p>1 2 3 4 5 6 7 8 Tuesday, April 9, 2024 9 9:27 a.m. Eastern Time 10 11 Expert Deposition of BERNARD L. 12 HARLOW, PHD, held at the offices of: 13 14 ASHCRAFT &amp; GEREL LLP 15 1825 K Street NW 16 Suite 700 17 Washington, DC 20006 18 19 Pursuant to notice, before Denise 20 Dobner Vickery, Certified Realtime Reporter, 21 Registered Merit Reporter, and Notary Public in 22 and for the District of Columbia. 23 24</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: 2 3 For New Jersey Plaintiffs: 4 ANAPOL WEISS 5 BY: TRACY A. FINKEN, ESQ. 6 One Logan Square 7 130 N. 18th Street, Suite 1600 8 Philadelphia, PA 19103 9 215.735.0773 10 tfinken@anapolweiss.com 11 12 13 14 For Defendants Johnson &amp; Johnson and Johnson &amp; 15 Johnson Consumer Inc.: 16 SHOOK HARDY &amp; BACON LLP 17 BY: MARK C. HEGARTY, ESQ. 18 2555 Grand Blvd. 19 Kansas City, MO 64108 20 816.474.6550 21 mhegarty@shb.com 22 23 24</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: 2 3 For Plaintiffs: 4 LEVIN PAPATONIO RAFFERTY PROCTOR 5 BUCHANAN O'BRIEN BARR &amp; MOUGEY, PA 6 BY: CHRISTOPHER V. TISI, ESQ. 7 316 South Baylen Street, Suite 600 8 Pensacola, FL 32502-5996 9 850.435.7999 10 ctisi@levinlaw.com 11 12 13 For MDL Plaintiffs: 14 ASHCRAFT &amp; GEREL LLP 15 BY: MICHELLE A. PARFITT, ESQ. 16 1825 K Street NW, Suite 700 17 Washington, DC 20006 18 202.759.7648 19 mparfitt@ashcraftlaw.com 20 21 22 23 24</p>	<p style="text-align: right;">Page 5</p> <p>1 INDEX 2 EXAMINATION OF BERNARD L. HARLOW, PHD PAGE 3 BY MR. HEGARTY 12 4 AFTERNOON SESSION 218 5 BY MR. TISI 418 6 FURTHER BY MR. HEGARTY 500 7 8 HARLOW DEPOSITION EXHIBITS 9 NUMBER DESCRIPTION PAGE 10 EXHIBIT 1 Harlow's 2 Binders of Documents 15 11 EXHIBIT 2 Harlow Invoices No. 1 - 3 20 12 EXHIBIT 3 Harlow Curriculum Vitae March 2024 42 13 EXHIBIT 4 Plaintiff's Designation of 60 14 Affirmative Experts 15 EXHIBIT 5 Expert Report of Bernard L. 76 16 Harlow, Ph.D. and Kenneth J. 17 Rothman, Dr.P.H. November 15, 2023 18 EXHIBIT 6 Genital Talc Exposure and Risk 83 19 Of Ovarian Cancer, Cramer et al 1998 20 EXHIBIT 7 The International Society of 92 21 Regulatory Toxicology and 22 Pharmacology and the US FDA 23 A Workshop, Talc: Consumer Uses and 24 Health Perspectives, January 31, 1994</p>

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<p style="text-align: right;">Page 7</p> <p>1 EXHIBIT 15 Talc/FDA Website. What's New 245</p> <p>2 December 7, 2022</p> <p>3 EXHIBIT 16 DHHS Letter of April 1, 2014 to 249</p> <p>4 Cancer Prevention Coalition re</p> <p>5 Denial of Citizen Petitions of</p> <p>6 November 17, 1994 and May 13, 2008</p> <p>7 EXHIBIT 17 NCI Ovarian, Fallopian Tube, and 270</p> <p>8 Primary Peritoneal Cancers</p> <p>9 Prevention (PDQ®) - Health</p> <p>10 Professional Version, March 6, 2024</p> <p>11 EXHIBIT 18 NCI PDQ® Screening and Prevention 276</p> <p>12 Editorial Board, February 28, 2024</p> <p>13 EXHIBIT 19 Association Between the Frequent 285</p> <p>14 Use of Perineal Talcum Powder</p> <p>15 Products and Ovarian Cancer: a</p> <p>16 Systematic Review and Meta-analysis</p> <p>17 Woolen et al, February 2, 2022</p> <p>18 EXHIBIT 20 Risk Factors of Epithelial 296</p> <p>19 Ovarian Cancer by Histologic</p> <p>20 Subtype, Gates et al, 2010</p> <p>21 EXHIBIT 21 Perineal use of talc and risk of 326</p> <p>22 ovarian cancer, Langseth et al</p> <p>23 15 October 2007</p> <p>24</p>	<p style="text-align: right;">Page 9</p> <p>1 EXHIBIT 28 Comment &amp; Response, Genital 379</p> <p>2 Powder Use and Ovarian Cancer</p> <p>3 JAMA May 26, 2020</p> <p>4 EXHIBIT 29 Data on systematic review and 398</p> <p>5 meta-analysis of epidemiologic</p> <p>6 evidence on the association between</p> <p>7 perineal use of talc powder and risk</p> <p>8 of ovarian cancer, Taher et al,</p> <p>9 5 February 2020</p> <p>10 EXHIBIT 30 Critical review of the 398</p> <p>11 association between perineal use</p> <p>12 of talc powder and risk of ovarian</p> <p>13 cancer, Taher et al, 23 August 2019</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p style="text-align: right;">Page 11</p> <p>1 EXHIBIT P7 Interpretation of Epidemiologic 467</p> <p>2 Studies on Talc and Ovarian Cancer,</p> <p>3 Rothman et al, November 28, 2000</p> <p>4 EXHIBIT P8 Association of genital talc and 477</p> <p>5 douche use in early adolescence or</p> <p>6 adulthood with uterine fibroids</p> <p>7 diagnoses, Ogunsina et al,</p> <p>8 December 2023</p> <p>9 EXHIBIT P9 Federal Register, 40 CFR 482</p> <p>10 Part 751 Asbestos Part 1;</p> <p>11 Chrysotile Asbestos; Regulation of</p> <p>12 Certain Conditions of Use Under</p> <p>13 the Toxic Substances Control Act</p> <p>14 (TSCA), March 28, 2024</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. Do you recall the deponents in those</p> <p>2 transcripts?</p> <p>3 A. I believe I read -- I read more</p> <p>4 Moor --</p> <p>5 Q. You can't look at him.</p> <p>6 A. Okay. I'm just -- I'm just --</p> <p>7 Moorman I believe I read.</p> <p>8 Q. Patricia Moorman?</p> <p>9 A. Patricia Moorman. I can't remember</p> <p>10 her name.</p> <p>11 Q. It's okay if you cannot remember.</p> <p>12 A. I can't remember. I can't remember</p> <p>13 the names.</p> <p>14 Q. You can only recall Dr. Moorman's?</p> <p>15 A. I recall Dr. Moorman, and there was</p> <p>16 one that was more recent. I mean, I could -- I</p> <p>17 just -- I can't remember the name.</p> <p>18 MR. TISI: Can I just and let</p> <p>19 me just say this because this is the</p> <p>20 first time you have testified, and I just</p> <p>21 want to make sure.</p> <p>22 He's going to be asking</p> <p>23 questions. Normally we kind of</p> <p>24 anticipate questions and we talk over</p>

<p style="text-align: right;">Page 14</p> <p>1 each other.</p> <p>2 It makes the record a lot</p> <p>3 easier for -- for Denise here if you</p> <p>4 allow -- allow Mr. Hegarty to finish his</p> <p>5 question and then give an answer, and I</p> <p>6 will make sure that Mr. Hegarty lets you</p> <p>7 finish your answer before he starts his</p> <p>8 next question.</p> <p>9 THE WITNESS: Sure.</p> <p>10 MR. HEGARTY: And I will cover</p> <p>11 that, too, but thank you.</p> <p>12 THE WITNESS: I'm sorry that</p> <p>13 I forgot the name.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. When did you read Dr. Moorman's</p> <p>16 deposition transcript?</p> <p>17 A. Probably within the last month.</p> <p>18 Q. Who did you receive that transcript</p> <p>19 and the other two transcripts from?</p> <p>20 A. From Dr. -- I mean, Mr. Tisi.</p> <p>21 Q. Did you make a request for those</p> <p>22 transcripts?</p> <p>23 A. I believe I indicated that it would</p> <p>24 be helpful, since I had never been deposed before,</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Other than those two notebooks, did</p> <p>2 you bring any other materials with you to today's</p> <p>3 deposition?</p> <p>4 A. No.</p> <p>5 Q. Did you prepare any notes in</p> <p>6 connection with your work on this case?</p> <p>7 A. No, I did not.</p> <p>8 Q. Did you prepare any other</p> <p>9 documents -- or let me start over.</p> <p>10 Did you prepare any documents</p> <p>11 besides your expert report for purposes of your</p> <p>12 work on this case?</p> <p>13 A. No, I did not.</p> <p>14 Q. Who is your current employer?</p> <p>15 A. Boston University School of Public</p> <p>16 Health.</p> <p>17 Q. Do you have a separate personal</p> <p>18 consulting business for litigation like an LLC?</p> <p>19 A. I do have an LLC.</p> <p>20 Q. Do you run your expert witness work</p> <p>21 through that LLC?</p> <p>22 A. I -- I must. I must.</p> <p>23 Q. What is the name of that LLC?</p> <p>24 A. Bernard L. Harlow.</p>
<p style="text-align: right;">Page 15</p> <p>1 to have a sense of the process.</p> <p>2 Q. What Mr. Tisi just said and as you</p> <p>3 just mentioned the process, it's important that</p> <p>4 you and I speak one at a time, that we speak</p> <p>5 audibly, and that you understand the questions</p> <p>6 that I ask before you answer.</p> <p>7 Are you good with all of those sort</p> <p>8 of ground rules?</p> <p>9 A. Yes.</p> <p>10 Q. Did you bring any documents with you</p> <p>11 to today's deposition?</p> <p>12 A. Yes.</p> <p>13 Q. What documents did you bring?</p> <p>14 A. Manuscripts of previously published</p> <p>15 papers and a few other publicly available</p> <p>16 information.</p> <p>17 Q. Are those materials contained in the</p> <p>18 two notebooks sitting in front of you?</p> <p>19 A. Yes.</p> <p>20 MR. HEGARTY: I will designate</p> <p>21 those two notebooks as Exhibit Number 1.</p> <p>22 (2 Notebooks marked for</p> <p>23 identification as Harlow Exhibit 1.)</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. How long have you had that LLC?</p> <p>2 A. About six months.</p> <p>3 Q. Did you set that LLC up in</p> <p>4 connection with your work on this litigation?</p> <p>5 A. Yes.</p> <p>6 Q. Do the fees that you earn as an</p> <p>7 expert witness go directly to you?</p> <p>8 A. Yes.</p> <p>9 Q. Do you have any other sources of</p> <p>10 income besides the salary you get from Boston</p> <p>11 University and whatever you earn as an expert</p> <p>12 witness?</p> <p>13 A. No.</p> <p>14 Q. You are charging Mr. Tisi and other</p> <p>15 attorneys representing plaintiffs \$600 an hour for</p> <p>16 your time; is that correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Do you charge a different rate for</p> <p>19 testimony versus your review of materials?</p> <p>20 A. No. I've never been -- I've never</p> <p>21 had to testify. So, but as of right now, no, I</p> <p>22 have not.</p> <p>23 Q. What did you base the \$600 an hour</p> <p>24 figure on? In other words, where did you come up</p>

<p style="text-align: right;">Page 18</p> <p>1 with that number?</p> <p>2 A. Through colleagues of mine who are</p> <p>3 attorneys, and I asked what was an appropriate</p> <p>4 amount.</p> <p>5 Q. What's a -- who's a colleague of</p> <p>6 yours that's an attorney that you had that</p> <p>7 discussion with?</p> <p>8 MR. TISI: Well, let me object</p> <p>9 to the extent he was asking any advice</p> <p>10 from -- from other lawyers about -- about</p> <p>11 what he should charge.</p> <p>12 You can give a general -- a</p> <p>13 general idea.</p> <p>14 MR. HEGARTY: All I'm asking</p> <p>15 for is a name.</p> <p>16 MR. TISI: Yeah, I understand.</p> <p>17 THE WITNESS: His name is</p> <p>18 Robert Adelman. He's an attorney in</p> <p>19 Connecticut.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. And with regard to this -- this \$600</p> <p>22 an hour figure, you don't make that much as a</p> <p>23 professor at Boston University, do you?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 20</p> <p>1 have been provided for you.</p> <p>2 (Document marked for</p> <p>3 identification as Harlow Exhibit 2.)</p> <p>4 MR. TISI: I assume this is</p> <p>5 Exhibit 2?</p> <p>6 MR. HEGARTY: Yes. As I said,</p> <p>7 I'm marking that as Exhibit Number 2.</p> <p>8 MR. TISI: Okay. I'm sorry.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Please look at Exhibit Number 2,</p> <p>11 Dr. Harlow, and tell us whether those are the</p> <p>12 invoices that you have issued in connection with</p> <p>13 your work in this case.</p> <p>14 A. Well, these are -- these are copies</p> <p>15 of the same invoice.</p> <p>16 Q. There are three separate invoices,</p> <p>17 correct?</p> <p>18 A. No. These all appear to be the same</p> <p>19 invoice.</p> <p>20 MR. TISI: Let me see. Maybe</p> <p>21 they collated them differently.</p> <p>22 I think -- I think I know what</p> <p>23 happened. Here you go. I think</p> <p>24 they're --</p>
<p style="text-align: right;">Page 19</p> <p>1 Q. Did you receive a retainer in</p> <p>2 connection with your work in this litigation?</p> <p>3 A. No.</p> <p>4 Q. Have you invoiced to the lawyers</p> <p>5 representing plaintiffs the time that you have</p> <p>6 spent working on this litigation?</p> <p>7 A. Yes.</p> <p>8 Q. Do you invoice as well expenses that</p> <p>9 you've incurred associated with your work on this</p> <p>10 litigation?</p> <p>11 A. Yes.</p> <p>12 Q. For example, you flew down here from</p> <p>13 Boston, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Did you fly first class?</p> <p>16 A. No.</p> <p>17 Q. Do you intend to invoice the cost of</p> <p>18 that flight to the attorneys representing</p> <p>19 plaintiffs in this case?</p> <p>20 A. Yes.</p> <p>21 Just looking for my water.</p> <p>22 MR. TISI: I'll get it.</p> <p>23 MR. HEGARTY: I'm going to</p> <p>24 mark as Exhibit Number 2 the invoices we</p>	<p style="text-align: right;">Page 21</p> <p>1 MR. HEGARTY: Okay.</p> <p>2 MR. TISI: I think they</p> <p>3 printed them.</p> <p>4 MR. HEGARTY: So do you have 1</p> <p>5 as well in your group?</p> <p>6 MR. TISI: I think you</p> <p>7 probably. I have --</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. There's 3.</p> <p>10 A. 2, 3. We're missing 1.</p> <p>11 MR. HEGARTY: Okay. Let's go</p> <p>12 off the record real quick.</p> <p>13 (Recess: 9:34 a.m. -</p> <p>14 9:36 a.m.)</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Does Boston University have</p> <p>17 disclosure policies for consulting outside of your</p> <p>18 work at the university?</p> <p>19 A. I believe it's only if it exceeds a</p> <p>20 certain amount.</p> <p>21 Q. Have you disclosed the work you are</p> <p>22 doing in this litigation pursuant to any</p> <p>23 disclosure policy at Boston University?</p> <p>24 A. No.</p>



<p style="text-align: right;">Page 22</p> <p>1 Q. You have not filled out any type of</p> <p>2 form disclosing that you're -- you have consulted</p> <p>3 with and are a designated expert witness for</p> <p>4 plaintiffs in this litigation?</p> <p>5 A. Not at this point. We do that at</p> <p>6 the end of the year. So if they ask about events</p> <p>7 that happened in the past year, I will evaluate.</p> <p>8 I look will look at the form that they provide and</p> <p>9 complete it accordingly.</p> <p>10 Q. You started working with the</p> <p>11 attorneys representing the plaintiffs in this case</p> <p>12 back in 2023, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Did you prepare any type of</p> <p>15 disclosure form for Boston University at the end</p> <p>16 of 2023?</p> <p>17 A. No, I did not.</p> <p>18 Q. You needed to do so, didn't you?</p> <p>19 A. I would have to check on that.</p> <p>20 Q. I've looked at the policies online,</p> <p>21 and from my review, it appears that you would need</p> <p>22 to fill out a disclosure form for your work on</p> <p>23 this case.</p> <p>24 Is that not your understanding?</p>	<p style="text-align: right;">Page 24</p> <p>1 research activities at Boston University?</p> <p>2 A. Yes.</p> <p>3 Q. What is the focus of your research</p> <p>4 currently?</p> <p>5 A. I'm currently studying unexplained</p> <p>6 vulvar pain. I'm also studying the impact of --</p> <p>7 of factors that influence women's urological</p> <p>8 health.</p> <p>9 Q. What percentage of your work time do</p> <p>10 you devote to this research?</p> <p>11 A. This year, about 50 percent.</p> <p>12 Q. Are you currently teaching students?</p> <p>13 A. This year, yes, I taught a class. I</p> <p>14 taught.</p> <p>15 Q. What class did you teach this year?</p> <p>16 A. This year I taught Guided</p> <p>17 Epidemiology Research.</p> <p>18 Q. Have you always taught classes while</p> <p>19 you've been at Boston University?</p> <p>20 A. Yes.</p> <p>21 Q. Besides teaching and research, what</p> <p>22 other activities do you do at Boston University</p> <p>23 work-wise?</p> <p>24 A. I sit on the -- I sit on committees.</p>
<p style="text-align: right;">Page 23</p> <p>1 A. I will check on that when I get</p> <p>2 back.</p> <p>3 Q. Have you orally or in any other type</p> <p>4 of writing advised anyone at Boston University</p> <p>5 about your work on this case?</p> <p>6 A. Only Dr. Rothman, who I had done</p> <p>7 work with.</p> <p>8 Q. Other than Dr. Rothman, did you</p> <p>9 advise anyone else at Boston University about your</p> <p>10 work on this litigation?</p> <p>11 A. No.</p> <p>12 Q. What do you consider your occupation</p> <p>13 to be?</p> <p>14 A. A professor of epidemiology.</p> <p>15 Q. What is your current area of</p> <p>16 expertise in epidemiology?</p> <p>17 A. Women's reproductive and gynecologic</p> <p>18 health.</p> <p>19 Q. Is there a particular subtype of</p> <p>20 those two categories that you're focused on</p> <p>21 currently?</p> <p>22 A. I'm currently focusing on benign</p> <p>23 gynecologic disorders.</p> <p>24 Q. Are you currently involved in any</p>	<p style="text-align: right;">Page 25</p> <p>1 I have -- I currently sit on the appointment and</p> <p>2 promotions committee for the -- for the school. I</p> <p>3 directed the master's of public health -- I</p> <p>4 codirected the master's of public health program</p> <p>5 in epidemiology and biostatistics. Those are the</p> <p>6 most recent.</p> <p>7 Q. What percentage of your work time do</p> <p>8 you spend on committees?</p> <p>9 A. 10 percent.</p> <p>10 Q. You told me that 50 percent goes to</p> <p>11 research, 10 percent to committees.</p> <p>12 Is then 40 percent devoted to</p> <p>13 teaching?</p> <p>14 A. About that, yes.</p> <p>15 Q. Are you affiliated in any way still</p> <p>16 with the University of Minnesota?</p> <p>17 A. I have an adjunct appointment, that</p> <p>18 my work on women's urological condition is a</p> <p>19 subcontract through the University of Minnesota.</p> <p>20 And as you know from my CV, I chaired the</p> <p>21 Department of Epidemiology there for 10 years.</p> <p>22 Q. How many hours a week do you</p> <p>23 typically put in at Boston University?</p> <p>24 A. Well, how many hours I put in?</p>



<p style="text-align: right;">Page 26</p> <p>1 Probably 40 to 50. (Laugh).</p> <p>2 Q. Okay. Have you taught courses at</p> <p>3 the medical school at Boston University?</p> <p>4 A. No.</p> <p>5 Q. You don't teach gynecologic</p> <p>6 oncologists, correct?</p> <p>7 A. No.</p> <p>8 Q. You don't teach oncologists,</p> <p>9 correct?</p> <p>10 A. No.</p> <p>11 Q. Prior to this case, have you ever</p> <p>12 been, to your knowledge, designated as an expert</p> <p>13 witness in a legal proceeding?</p> <p>14 A. No.</p> <p>15 Q. What percentage of your work time in</p> <p>16 2023 was spent on litigation matters?</p> <p>17 A. 10 percent, maybe less.</p> <p>18 Q. What percentage of your work time in</p> <p>19 2024 has been spent on litigation matters?</p> <p>20 A. About the same.</p> <p>21 Q. In 2023, what percentage of your</p> <p>22 total income was from work on litigation matters?</p> <p>23 A. I would say less than 10 percent.</p> <p>24 Q. Are you consulting with regard to</p>	<p style="text-align: right;">Page 28</p> <p>1 case or cases involving talcum powder use and</p> <p>2 ovarian cancer?</p> <p>3 A. Yeah. I did provide consultation on</p> <p>4 an area of acetaminophen use in pregnant women and</p> <p>5 its association with neurodevelopmental disorders.</p> <p>6 Q. That --</p> <p>7 A. I was not an expert.</p> <p>8 Q. That consultation has been</p> <p>9 publicized in the press and on the internet,</p> <p>10 correct?</p> <p>11 A. That is correct.</p> <p>12 Q. In fact, there is an article that</p> <p>13 reports that you serve on a lawyer-sponsored</p> <p>14 Autism Justice's team of experts?</p> <p>15 A. I had, correct. I don't know if I'm</p> <p>16 still involved.</p> <p>17 Q. That team includes Erin Brockovich,</p> <p>18 correct?</p> <p>19 A. That is correct.</p> <p>20 Q. And with regard to that</p> <p>21 consultation, again, those are -- that</p> <p>22 consultation has been related to claims that</p> <p>23 acetaminophen use during pregnancy causes autism?</p> <p>24 A. Correct.</p>
<p style="text-align: right;">Page 27</p> <p>1 litigation on any matters other than matters</p> <p>2 involving talcum powder and ovarian cancer?</p> <p>3 A. Currently, no.</p> <p>4 Q. Have you ever consulted on any</p> <p>5 litigation matters besides cases involving talcum</p> <p>6 powder use and claims of ovarian cancer?</p> <p>7 A. Could you just repeat that, please?</p> <p>8 Q. Sure.</p> <p>9 Have you ever consulted on a</p> <p>10 litigation matter other than in cases involving</p> <p>11 talcum powder use and ovarian cancer claims?</p> <p>12 MR. TISI: And the answer is</p> <p>13 yes or no, just to be clear. He's not</p> <p>14 asking you what you did, just whether you</p> <p>15 did.</p> <p>16 MR. HEGARTY: That's right.</p> <p>17 THE WITNESS: I'm not sure</p> <p>18 what "litigation matter" means. If you</p> <p>19 could define that for me?</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Sure.</p> <p>22 Have you ever consulted on what you</p> <p>23 understood was a legal proceeding or a lawsuit,</p> <p>24 besides what we're here to talk about today, a</p>	<p style="text-align: right;">Page 29</p> <p>1 Q. Also that acetaminophen use during</p> <p>2 pregnancy causes ADHD; is that correct?</p> <p>3 A. It's the entire spectrum of</p> <p>4 neurodevelopmental disorders.</p> <p>5 Q. Have you been paid anything for your</p> <p>6 consultation work as to that subject area?</p> <p>7 A. Yes.</p> <p>8 Q. How much have you been paid?</p> <p>9 A. I would have to -- to go back, but</p> <p>10 it was -- I would be surprised if it was more than</p> <p>11 \$5,000. It may have been less. I just -- I don't</p> <p>12 remember.</p> <p>13 Q. Is that consultation work still</p> <p>14 ongoing?</p> <p>15 A. Not that I'm aware of.</p> <p>16 Q. When did you last, as you understand</p> <p>17 it serve, as a consult -- as a consultant in that</p> <p>18 litigation -- in that subject area?</p> <p>19 A. Probably I would think earlier,</p> <p>20 prior to my work on this, in I believe it was</p> <p>21 2023.</p> <p>22 Q. Is it your opinion that</p> <p>23 acetaminophen use during pregnancy causes autism?</p> <p>24 MR. TISI: Objection.</p>

<p style="text-align: right;">Page 30</p> <p>1 Objection to the extent to which you</p> <p>2 develop that in the course of your</p> <p>3 consultation. He can ask you about your</p> <p>4 published work, but -- but anything you</p> <p>5 developed in the course of your</p> <p>6 consultation with those attorneys, I</p> <p>7 instruct you not to answer.</p> <p>8 MR. HEGARTY: Wait. Let me</p> <p>9 clarify. I'm asking him without regard</p> <p>10 to consultation.</p> <p>11 MR. TISI: If you develop --</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Is it your opinion?</p> <p>14 MR. TISI: If you develop that</p> <p>15 opinion in connection with your</p> <p>16 consultation work, I instruct you not to</p> <p>17 answer that question.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Are you going to follow Mr. Tisi's</p> <p>20 instructions?</p> <p>21 A. Yes.</p> <p>22 MR. HEGARTY: What's the basis</p> <p>23 of that objection?</p> <p>24 MR. TISI: He developed -- he</p>	<p style="text-align: right;">Page 32</p> <p>1 A. Yes.</p> <p>2 Q. What was the relative risk or odds</p> <p>3 ratio that you came up -- came away with from your</p> <p>4 review of that literature?</p> <p>5 MR. TISI: Again, I'm going to</p> <p>6 instruct you if you developed that --</p> <p>7 THE WITNESS: I just --</p> <p>8 MR. TISI: Wait. Let me</p> <p>9 finish.</p> <p>10 If you developed that in the</p> <p>11 context of your consultation with lawyers</p> <p>12 to advise lawyers about pending</p> <p>13 litigation in legal matters, then I</p> <p>14 instruct you not to answer that question.</p> <p>15 If you did it otherwise, then feel free</p> <p>16 to answer the question.</p> <p>17 THE WITNESS: I did not.</p> <p>18 I'm sorry. Repeat the</p> <p>19 question, please.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Sure.</p> <p>22 Did you develop an opinion as to the</p> <p>23 odds ratio of relative risk of neurologic</p> <p>24 disorders, including autism, from acetaminophen</p>
<p style="text-align: right;">Page 31</p> <p>1 developed an opinion. Unless he</p> <p>2 expressed it publicly. Okay? You can</p> <p>3 ask him about his public statements, but</p> <p>4 if he expressed it -- if he developed an</p> <p>5 opinion and he expressed it to lawyers,</p> <p>6 he developed it during consultation.</p> <p>7 And if you -- if you disagree</p> <p>8 with me, I'm more than happy --</p> <p>9 MR. HEGARTY: That's all</p> <p>10 right. We're not -- I do disagree with</p> <p>11 you, but we're not going to be -- it's</p> <p>12 not going to be resolved here.</p> <p>13 MR. TISI: Okay.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Have you ever made any public</p> <p>16 statement that acetaminophen use during pregnancy</p> <p>17 causes autism or any other neurologic disorder?</p> <p>18 A. I made a public statement that there</p> <p>19 was evidence of an association. I do not believe</p> <p>20 I ever used the word "cause."</p> <p>21 Q. Did you make the statement that</p> <p>22 there was evidence of an association based on your</p> <p>23 review of all the epidemiologic studies looking at</p> <p>24 acetaminophen use and neurologic disorders?</p>	<p style="text-align: right;">Page 33</p> <p>1 use during pregnancy?</p> <p>2 A. I did not develop an opinion. I</p> <p>3 reviewed the literature as to what had been</p> <p>4 published.</p> <p>5 Q. Did you come away with an opinion as</p> <p>6 to whether the studies showed a dose response?</p> <p>7 A. I don't recall.</p> <p>8 Q. Did you look at any animal studies</p> <p>9 related to acetaminophen use during pregnancy and</p> <p>10 autism or neurologic disorders?</p> <p>11 A. I looked at biological, yes. Yes.</p> <p>12 Q. You looked at biologic plausibility</p> <p>13 studies?</p> <p>14 A. Yes.</p> <p>15 Q. Those included animal studies?</p> <p>16 A. Again, I don't recall. I would have</p> <p>17 to go back.</p> <p>18 Q. Do you remember if you looked at any</p> <p>19 cell studies?</p> <p>20 A. I don't recall.</p> <p>21 Q. Did you compare competing</p> <p>22 explanations for any positive increase in risk</p> <p>23 from acetaminophen use during pregnancy and</p> <p>24 autism?</p>

<p style="text-align: right;">Page 34</p> <p>1 A. Absolutely. That is the way in 2 which I usually evaluate scientific literature. 3 Q. Did those competing risks include 4 genetics or -- just leave it at that. 5 A. I don't recall. 6 MR. TISI: I don't want to 7 interrupt you, but it looks like we're on 8 mute and for some reason Tracy can't hear 9 us. 10 MR. HEGARTY: Okay. Let's go 11 off the record. 12 MS. FINKEN: No, I can hear. 13 MR. TISI: You can hear now? 14 MS. FINKEN: Yes. 15 MR. TISI: Okay. Sorry. 16 BY MR. HEGARTY: 17 Q. Sounds like from your last response 18 you applied the same methodology in looking at the 19 epidemiologic studies on acetaminophen use during 20 pregnancy and autism as you did for this case? 21 A. That's correct. 22 Q. Have you ever been hired by a 23 company to consult regarding a cosmetic product? 24 A. No.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. Have you ever served on an FDA 2 committee? 3 A. Only the conference that was held in 4 1994, I believe, that was sponsored by the FDA. I 5 was an invited participant. 6 Q. And we'll talk about that here in a 7 moment. 8 A. Yeah. 9 Q. Other than that, other than your 10 participation in that 1994 FDA workshop -- 11 A. Yes. 12 Q. -- have you ever otherwise served on 13 any FDA committee or been otherwise involved in 14 FDA with regard to a cosmetic including talcum 15 powder? 16 A. Yeah. No. 17 Q. FDA has never contacted you about 18 talcum powder, correct? 19 A. No. 20 Q. You have never worked for Health 21 Canada, correct? 22 A. Correct. 23 Q. You have never worked for any 24 foreign regulatory agency, correct?</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Has any cosmetic pharmaceutical or 2 chemical company ever hired you as a consultant on 3 any matter? 4 A. No. 5 Q. Have you ever been employed by a 6 pharmaceutical medical device consumer product or 7 chemical company in any capacity? 8 A. No. 9 Q. Have you ever been involved in a 10 company's analysis of safety data regarding a 11 cosmetic? 12 A. No. 13 Q. You have never worked for FDA, 14 correct? 15 A. Correct. 16 Q. Have you ever worked for any 17 governmental agency, that is, been employed by a 18 governmental agency? 19 A. Yes. Oh, employed by a government 20 agency. No. 21 Q. Have you ever communicated directly 22 with anyone at FDA regarding a cosmetic including 23 talcum powder? 24 A. No.</p>	<p style="text-align: right;">Page 37</p> <p>1 A. Correct. 2 Q. You have never communicated with 3 Health Canada? 4 A. Correct. 5 Q. Have you ever referenced in any 6 publication of yours a finding by Health Canada? 7 A. No. 8 Q. Have you ever referenced in any 9 publication of yours a Health Canada risk 10 assessment? 11 A. Only the report that I currently 12 wrote. 13 Q. My question was specifically as to a 14 publication. 15 Your report has not been published, 16 correct? 17 A. Correct. 18 Q. So have you ever referenced in any 19 publication of yours a Health Canada risk 20 assessment? 21 A. No. 22 Q. Do you claim to be an expert in 23 Health Canada's risk assessment process? 24 A. Yes.</p>

<p style="text-align: right;">Page 38</p> <p>1 Q. What is the basis of your expertise?</p> <p>2 A. I believe I'm an accomplished</p> <p>3 epidemiologist that's able to evaluate the</p> <p>4 strengths and limitations of the evaluation of</p> <p>5 scientific literature.</p> <p>6 Q. My question might be a little bit</p> <p>7 different.</p> <p>8 My question is: Are you an expert</p> <p>9 in the process by which Health Canada goes about</p> <p>10 doing its risk assessments?</p> <p>11 A. No.</p> <p>12 MR. TISI: Objection. Vague.</p> <p>13 THE WITNESS: Sorry.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. You have read Health Canada's</p> <p>16 screening assessment for talc, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Did you have any dealings with</p> <p>19 Health Canada as it relates to that screening</p> <p>20 assessment?</p> <p>21 A. No.</p> <p>22 Q. Did you read Health Canada's</p> <p>23 screening assessment for talc prior to being</p> <p>24 contacted by plaintiffs' counsel about testifying</p>	<p style="text-align: right;">Page 40</p> <p>1 doing its screening assessment? In other words,</p> <p>2 had you heard about it before you were contacted</p> <p>3 by plaintiffs' counsel for this litigation?</p> <p>4 A. No, I was not.</p> <p>5 Q. You have reviewed the screening</p> <p>6 assessment, and from your review, did you note</p> <p>7 that it does reference or include as references</p> <p>8 plaintiff expert reports from U.S. litigation?</p> <p>9 MR. TISI: Objection.</p> <p>10 Incomplete.</p> <p>11 THE WITNESS: In my review, I</p> <p>12 did not -- I only looked at the studies</p> <p>13 and the evaluation that they did. I did</p> <p>14 not consider who did it, who was paid by</p> <p>15 whom to do what, or anything really</p> <p>16 regarding litigation.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Have you ever cited to litigation</p> <p>19 reports in any peer-reviewed publication of yours?</p> <p>20 A. No, not that I'm aware of.</p> <p>21 Q. Have you ever cited to any expert</p> <p>22 litigation testimony in any peer-reviewed</p> <p>23 publication of yours?</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 39</p> <p>1 as an expert for them in this litigation?</p> <p>2 A. I did not.</p> <p>3 Q. Do you know who the authors of</p> <p>4 Health Canada's screening assessment are?</p> <p>5 A. I do not.</p> <p>6 Q. Do you know anyone involved in</p> <p>7 analyzing the data and putting that screening</p> <p>8 assessment together?</p> <p>9 A. No.</p> <p>10 Q. Do you know the expertise of anyone</p> <p>11 involved in putting the screening assessment</p> <p>12 together for talc?</p> <p>13 A. In the Health Canada report?</p> <p>14 Q. Yes, sir.</p> <p>15 A. No.</p> <p>16 Q. Did you review any of the materials</p> <p>17 submitted to Health Canada as part of that</p> <p>18 process?</p> <p>19 A. No.</p> <p>20 Q. You did not submit any material to</p> <p>21 Health Canada as part of the screening assessment</p> <p>22 process, correct?</p> <p>23 A. Correct.</p> <p>24 Q. Did you know that Health Canada was</p>	<p style="text-align: right;">Page 41</p> <p>1 Q. Do you know whether FDA has ever</p> <p>2 cited to any litigation expert reports or</p> <p>3 testimony in making any safety findings or</p> <p>4 conclusions?</p> <p>5 MR. TISI: Objection.</p> <p>6 Only if you know.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. Have you ever cited to exhibits from</p> <p>10 depositions in any peer-reviewed publication of</p> <p>11 yours?</p> <p>12 A. No.</p> <p>13 Q. Do you think it's appropriate for an</p> <p>14 entity such as Health Canada to rely on litigation</p> <p>15 reports for purposes of putting together that</p> <p>16 screening assessment?</p> <p>17 MR. TISI: Again, let me</p> <p>18 object. Assuming facts not in evidence.</p> <p>19 Go ahead.</p> <p>20 THE WITNESS: I have -- I</p> <p>21 don't -- I have no opinion on that.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. I asked you earlier about your</p> <p>24 consulting work.</p>

<p style="text-align: right;">Page 42</p> <p>1 Are you currently consulting, 2 outside of what we're here to talk about today, 3 cases involving talcum powder use and ovarian 4 cancer? 5 A. No. 6 MR. HEGARTY: The next exhibit 7 I'm going to mark, Dr. Harlow, is a copy 8 of the CV we were provided in advance of 9 your deposition. It's dated at the top 10 March 2024. 11 THE WITNESS: Uh-huh. 12 MR. HEGARTY: I'm going to 13 mark that document as Exhibit 3. 14 (Document marked for 15 identification as Harlow Exhibit 3.) 16 THE WITNESS: Uh-huh. 17 BY MR. HEGARTY: 18 Q. Is Exhibit 3 your March 2024 19 curriculum vitae? 20 A. Yes. 21 Q. Does it accurately describe your 22 education, training, and experience? 23 A. Yes. 24 Q. Are there any changes or revisions</p>	<p style="text-align: right;">Page 44</p> <p>1 first -- 2 MR. HEGARTY: That's what I 3 was going to say. Let's go off the 4 record. 5 (Recess: 9:57 a.m. - 6 10:01 a.m.) 7 BY MR. HEGARTY: 8 Q. Dr. Harlow, we took a short break 9 after you and I discussed when you were first 10 being -- when you were first contacted about 11 serving as an expert witness in this litigation, 12 and in doing so, I want to circle back to your 13 invoices that we marked as Exhibit Number 2. 14 Do you have the three invoices that 15 we have been provided dated October 2023, January 16 2024 and February -- and January/February 2024? 17 A. Yes. 18 Q. Those have all been marked as 19 Exhibit Number 2 -- 20 A. Yes. 21 Q. -- is that correct? 22 A. Yes. 23 Q. And looking at Exhibit Number 2 and 24 the dates shown on it, can you tell when it was</p>
<p style="text-align: right;">Page 43</p> <p>1 necessary to make it current for today? 2 A. I don't believe so. 3 Q. Are your publications list up to 4 date? 5 A. I believe so, though things are 6 fluid with papers that are currently under review, 7 but this is largely correct. 8 Q. We are here today to take your 9 deposition in the case of In re Johnson &amp; Johnson 10 Talc Litigation MDL, et al. 11 Are you aware that you are 12 designated as a testifying expert in this case? 13 A. I know that I am a testifying expert 14 in -- in this litigation. I don't know who the 15 plaintiffs are. 16 Q. And we'll cover that here in a 17 moment, but when were you first contacted about 18 serving as an expert in this case? 19 A. In 2023. 20 Q. Do you recall the exact month and 21 date? 22 A. I would say perhaps August or 23 September or somewhere in that realm. I could 24 certainly look on my invoices to see when I</p>	<p style="text-align: right;">Page 45</p> <p>1 that you were first contacted about serving as an 2 expert witness in this litigation? 3 A. Well, it looks like I didn't start 4 doing work until toward the latter part of 5 September, but I may have been contacted before. 6 I was probably contacted before and didn't get 7 started on doing the work until -- until then. 8 Q. Are you able to recall how long it 9 was? 10 MR. TISI: I'm sorry. I don't 11 think he was finished. 12 BY MR. HEGARTY: 13 Q. Oh, I'm sorry. 14 A. No. Probably perhaps in August. 15 Q. Looking at Exhibit Number 2, the 16 first entry for the October 2023 invoice, it says 17 "Review of documents provided." 18 Who provided documents to you? 19 A. Mr. Tisi. 20 Q. What documents were you provided? 21 MR. TISI: Objection. I 22 instruct you not to answer what you were 23 provided. 24 BY MR. HEGARTY:</p>



<p style="text-align: right;">Page 46</p> <p>1 Q. Did you ask Mr. Tisi for any 2 documents in connection with your work on this 3 litigation?</p> <p>4 MR. TISI: You can answer that 5 question, but no further questions on 6 that.</p> <p>7 THE WITNESS: Only to the 8 extent that -- that it would be more 9 efficient with my time if they had the 10 list of -- a list of references of -- of 11 articles so that I wouldn't have to spend 12 my time doing a Medline search and having 13 to pull them all out on my own.</p> <p>14 Even though I did a Medline 15 search on the literature, I tried to be 16 efficient with my time.</p> <p>17 BY MR. HEGARTY: 18 Q. How many documents were you provided 19 by Mr. Tisi's office?</p> <p>20 A. I don't recall, but certainly no -- 21 not -- no more than what I've already -- what I 22 already have here. So.</p> <p>23 Q. You say what you already have here. 24 You're referring to the two</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. Looking down at the entries for 2 October 8th and 9th, it says "Review edits by KJR 3 and modify report."</p> <p>4 KJR is Ken Rothman?</p> <p>5 A. Correct.</p> <p>6 Q. How were those edits communicated to 7 you?</p> <p>8 A. We -- we worked together 9 collaboratively. We were either in person, but 10 most of the time it was on Zoom.</p> <p>11 Q. Were there drafts prepared that you 12 still have of your report?</p> <p>13 A. No. We -- we would modify existing 14 drafts and we would not keep the old ones.</p> <p>15 Q. The entry for October 10, 2023 says 16 "Met with KJR and then modified report." 17 Did you meet with him in person?</p> <p>18 A. I don't recall.</p> <p>19 Q. Looking at the bottom, under Total 20 it says "Total received: 9,000. Balance due: 21 4500."</p> <p>22 Is that 9,000 not a retainer?</p> <p>23 A. No, it is not a retainer.</p> <p>24 Q. Where is that -- where did that</p>
<p style="text-align: right;">Page 47</p> <p>1 notebooks we've marked as Exhibit Number 2? 2 A. The two notebooks, yes.</p> <p>3 Q. If you had the time, could you go 4 through the notebooks and identify which documents 5 that Mr. Tisi provided to you and which you 6 obtained on your own?</p> <p>7 A. I don't believe I'd be able to make 8 that separation.</p> <p>9 Q. The next two entries -- well, first 10 of all, before I go there, did you read all the 11 documents that Mr. Tisi's office provided to you?</p> <p>12 A. I read all the literature that he 13 provided, yes.</p> <p>14 Q. The next couple entries refer to 15 "Review of current epi studies." 16 How many epi studies does that refer 17 to?</p> <p>18 A. I don't recall.</p> <p>19 Q. The next one says "Review of current 20 literature." 21 Is that different than epi studies?</p> <p>22 A. It's a combination of both, of both 23 epi studies and other articles in the scientific 24 literature that are relevant.</p>	<p style="text-align: right;">Page 49</p> <p>1 9,000 come from?</p> <p>2 A. It was the first installment. I 3 originally was charging \$400 an hour and after 4 discussion realized that I was underestimating my 5 expert -- my expertise, and so I raised my hourly 6 rate to \$600.</p> <p>7 Q. What does it mean on the first page 8 of Exhibit Number 2 where it says "Total received: 9 9,000. Balance due: 4500"?</p> <p>10 A. The 9,000 was equated to these hours 11 at a rate of \$400 per hour, and then when we 12 changed it to 600, that's what was added in.</p> <p>13 Q. Please turn to your January 2024 14 invoice, invoice number 2.</p> <p>15 A. Yes.</p> <p>16 Q. At the top, the entry dated 17 October 23, 2023, it says "Discussion of Draft 18 Report Submitted." 19 Who was that discussion with?</p> <p>20 A. With Mr. Tisi and his colleagues.</p> <p>21 Q. What other -- who -- what colleagues 22 besides Mr. Tisi?</p> <p>23 A. I believe Michelle. I believe it 24 was only Michelle. Maybe Leigh O'Dell as well. I</p>

<p style="text-align: right;">Page 50</p> <p>1 just -- I don't exactly recall.</p> <p>2 Q. The next several entries say "Report</p> <p>3 Modification."</p> <p>4 What does "report modification"</p> <p>5 mean?</p> <p>6 A. We -- we modified based on other</p> <p>7 review of our report by Mr. Tisi and his</p> <p>8 colleagues. Not to change our opinions about</p> <p>9 anything but to elaborate in certain areas.</p> <p>10 Q. With regard to the "Discussion of</p> <p>11 Draft Report Submitted," was Dr. Rothman involved</p> <p>12 in that discussion, too?</p> <p>13 A. Yes.</p> <p>14 Q. The next several entries regarding</p> <p>15 revisions and modifications of your report, did</p> <p>16 you do this, those revisions and modifications,</p> <p>17 using the same process you told me a moment ago</p> <p>18 where you were working with a living document?</p> <p>19 A. Yes.</p> <p>20 Q. The 11/8/2023 entry says "Meeting</p> <p>21 with Ken and additional revisions."</p> <p>22 Was that an in-person meeting?</p> <p>23 A. I don't recall.</p> <p>24 Q. The November 10, 2023 entry says</p>	<p style="text-align: right;">Page 52</p> <p>1 the colleagues involved in that deposition</p> <p>2 preparation meeting?</p> <p>3 A. I'm sorry. I'm not that good with</p> <p>4 names. (Laugh).</p> <p>5 Q. Was that deposition preparation</p> <p>6 meeting in person or by phone?</p> <p>7 A. By -- by Zoom.</p> <p>8 Q. Please turn to your invoice</p> <p>9 number 3, January/February 2024.</p> <p>10 A. Uh-huh.</p> <p>11 Q. At the top, the entry for January 8,</p> <p>12 2024 says "Meeting to discuss deposition."</p> <p>13 Was that again with Mr. Tisi and</p> <p>14 colleagues?</p> <p>15 A. Yes.</p> <p>16 Q. Was that in person or on Zoom?</p> <p>17 A. On Zoom. All of our meetings have</p> <p>18 been on Zoom, other than when I came down to DC.</p> <p>19 Q. With regard to your coming down to</p> <p>20 DC, when did you come down to DC?</p> <p>21 A. Actually, may I correct that</p> <p>22 response?</p> <p>23 Q. Sure.</p> <p>24 A. I did have an in-person meeting the</p>
<p style="text-align: right;">Page 51</p> <p>1 "Legal team meeting and additional revisions."</p> <p>2 Who is "legal team"?</p> <p>3 A. Mr. Tisi and his colleagues.</p> <p>4 Q. Do you recall the names of any of</p> <p>5 his colleagues?</p> <p>6 A. Again, it would -- it would -- I</p> <p>7 don't -- I mean, it would possibly be Ms. --</p> <p>8 Ms. O'Dell and Michelle. There might have been</p> <p>9 other people on the call with us.</p> <p>10 Q. That was what I was going to ask you</p> <p>11 next.</p> <p>12 Was that legal team meeting in</p> <p>13 person or on the phone?</p> <p>14 A. Zoom.</p> <p>15 Q. The final entry on that invoice says</p> <p>16 "Deposition preparation."</p> <p>17 Was that deposition preparation with</p> <p>18 someone else --</p> <p>19 A. Yes.</p> <p>20 Q. -- or was that on your own?</p> <p>21 A. No, no. Yes. That would -- I'm</p> <p>22 sorry. That was not on my own. It was with</p> <p>23 Mr. Tisi and colleagues.</p> <p>24 Q. Do you recall the names of any of</p>	<p style="text-align: right;">Page 53</p> <p>1 week before I came down in Boston with Mr. Tisi</p> <p>2 and Michelle, and then -- and then this week when</p> <p>3 I came down.</p> <p>4 Q. How long was that the meeting last</p> <p>5 week?</p> <p>6 A. About seven hours.</p> <p>7 Q. You said you came down from Boston</p> <p>8 to DC yesterday; is that correct?</p> <p>9 A. On Monday.</p> <p>10 Q. On Monday.</p> <p>11 Did you meet with Mr. Tisi and</p> <p>12 Ms. Parfitt yesterday?</p> <p>13 A. Yesterday evening, yes.</p> <p>14 Q. How long did you meet yesterday</p> <p>15 evening?</p> <p>16 A. About one to two hours.</p> <p>17 Q. The meeting yesterday and the</p> <p>18 meeting last week were the only in-person meetings</p> <p>19 you had with Mr. Tisi and Ms. Parfitt?</p> <p>20 A. That's correct.</p> <p>21 Q. The other entries here with regard</p> <p>22 to deposition preparation with lawyers, for</p> <p>23 example, that was again by Zoom?</p> <p>24 A. Correct.</p>



<p style="text-align: right;">Page 54</p> <p>1 Q. The depo prep meeting with lawyers, 2 that was by Zoom? 3 A. That's correct. 4 Oh, there's the name of the other 5 deposition that I had reviewed. 6 Q. Who is that? 7 A. Dr. Osan. 8 Q. This invoice also refers to you 9 reviewing Dr. Osan's report, correct? 10 A. That's correct. 11 Q. Did you review her expert report for 12 this litigation? 13 A. I believe I reviewed the deposition. 14 Q. So where it says "report," it should 15 be deposition? 16 A. I think it should be, actually. 17 Q. The entry of February 28, 2024 18 refers to your review of Dr. Moorman's deposition, 19 which you talked about earlier, right? 20 A. Yes. 21 Q. There's also the last entry -- or 22 let me start over. 23 The last entry refers to "Deposition 24 preparation with lawyers."</p>	<p style="text-align: right;">Page 56</p> <p>1 since February 29, 2024? 2 A. Maybe 20. It might be more because 3 of the long session that we had last week and, 4 obviously, what is occurring today. So, but other 5 than that, I would say it is less than 20 hours. 6 Q. Going back to when you were first 7 contacted about serving as an expert witness in 8 this case, who contacted you? 9 A. Dr. Rothman. 10 Q. Did he tell you who had contacted 11 him about serving as an expert witness in this 12 litigation? 13 A. I believe he must have mentioned -- 14 he mentioned the name of the people he was working 15 with. 16 Q. Do you recall whose name he 17 mentioned, or names? 18 A. I really -- I really don't recall 19 that, until we had our first meeting, and then I 20 was introduced to Mr. Tisi. 21 Q. Was your first meeting prior to this 22 November -- this September 26, 2023 date on your 23 first invoice? 24 A. No, it would not have been because I</p>
<p style="text-align: right;">Page 55</p> <p>1 Was that again Mr. Tisi and 2 colleagues? 3 A. Yes. 4 Q. Again by Zoom? 5 A. Yes. 6 Q. With regard to Dr. Osan, was she the 7 only defense expert's testimony that you have 8 reviewed for your work on this case? 9 A. Yes. 10 Q. With regard to the invoices that 11 we've been looking at, have you been paid for the 12 amounts shown in the invoices? 13 A. Yes. 14 Q. Have you prepared any additional 15 invoices for further work you have done since the 16 date of this last invoice? 17 A. I have not submitted any invoices. 18 Q. Have you recorded the number of 19 hours you have spent working on this litigation 20 since September -- I'm sorry -- since February 29, 21 2024? 22 A. Yes. 23 Q. Do you know approximately how many 24 hours you have spent working on this litigation</p>	<p style="text-align: right;">Page 57</p> <p>1 would have invoiced for it. 2 Q. What did Dr. Rothman initially tell 3 you about potentially serving as an expert witness 4 in this litigation? 5 A. He didn't specifically ask me to be 6 an expert witness. He asked me to work with him 7 on preparing a report on the current scientific 8 evidence. 9 Q. When did you become aware that that 10 report would be an expert report for litigation 11 purposes? 12 A. After discussion with Mr. Tisi and 13 others. 14 Q. What did you understand prior to the 15 discussion with Mr. Tisi and others about why you 16 and Dr. Rothman were writing a report about talcum 17 powder and ovarian cancer? 18 A. Oh, I knew it was with respect to 19 litigation. 20 Q. There was never an understanding 21 that this would be for publication in a 22 peer-reviewed journal, correct? 23 A. That is correct. 24 Q. Prior to Dr. Rothman contacting you</p>

<p style="text-align: right;">Page 58</p> <p>1 about potentially serving as an expert witness in 2 this litigation, or what ultimately became serving 3 as an expert witness in this litigation, had you 4 ever been contacted by any plaintiff's lawyer 5 about serving as an expert witness in a case 6 involving talcum powder use? 7 A. Not as an expert witness. 8 Q. Had you ever been contacted by any 9 lawyer about cases involving talcum powder use to 10 serve in any capacity? 11 A. Yes. 12 Q. Who contacted you about serving in 13 any capacity in cases involving talcum powder use? 14 A. I -- 15 MR. TISI: I'm sorry. What 16 was the question? I'm sorry. The phone 17 went off so I missed it. 18 MR. HEGARTY: Sure. 19 BY MR. HEGARTY: 20 Q. Who contacted you initially -- or 21 strike that. 22 Who contacted you about serving in 23 the capacity as a consultant in cases involving 24 talcum powder use?</p>	<p style="text-align: right;">Page 60</p> <p>1 And then I had not done any work as after, I 2 believe, 2017. 3 Q. Do you recall how much you invoiced 4 as part of that work? 5 A. I would say it was less than 6 \$20,000. 7 Q. How much were you charging an hour 8 for that consultation work? 9 A. I would have to go back and look, 10 but it was less than 400. It might have been 200. 11 I don't recall. It was probably in that range of 12 2 to 400. 13 Q. To your knowledge, were you ever 14 disclosed as a testifying expert by these lawyers 15 or other lawyers prior to your disclosure in this 16 case? 17 A. Not that I'm aware of. 18 MR. HEGARTY: I'm going to 19 show you what I'm marking as Exhibit 20 Number 4. 21 (Document marked for 22 identification as Harlow Exhibit 4.) 23 BY MR. HEGARTY: 24 Q. This is a designation of -- well,</p>
<p style="text-align: right;">Page 59</p> <p>1 MR. TISI: You may answer that 2 question. 3 THE WITNESS: Members of 4 certain law firms, and I would have to 5 pull up to tell you exactly who those 6 individuals were because I just don't 7 recall their names. 8 BY MR. HEGARTY: 9 Q. When you say "pull up," what would 10 you have to look at? 11 A. I would -- I would look at invoices 12 that I -- that I provide -- I submitted to them 13 and that would -- yeah. 14 Q. Do you recall the names of any of 15 the law firms? 16 A. Sorry. I'm not that good with 17 names. I would have to go back and look, 18 especially law firms. (Laugh). 19 Q. Do you remember when it was you were 20 initially contacted about serving as a consultant 21 by these law firms? 22 A. Yes. It was, I think, I believe it 23 was around 2015 or 2016, and I believe it was over 24 a two-year period collectively, maybe three years.</p>	<p style="text-align: right;">Page 61</p> <p>1 this is called -- this is a document titled 2 "Plaintiff's Designation of Affirmative Experts" 3 in the case of Chakalos versus Johnson &amp; Johnson. 4 A. Uh-huh. 5 Q. Please turn over to the second page, 6 and do you see where you're listed? 7 A. Yes. 8 Q. Have you ever seen this designation 9 or this document before today? 10 A. No, I don't -- I don't believe so. 11 I'm looking to make sure I didn't 12 sign anything. (Laugh). No. 13 Q. Please look at the last page. 14 Do you recognize -- last two pages. 15 Do you recognize any of those names? 16 A. Oh, right. 17 Yes. Yes. Carmen Scott from Motley 18 Rice, yes. 19 Q. Do you recognize any other names? 20 A. Well, Meghan Carter, I believe, yes. 21 I don't believe I know -- I remember the others, 22 any others. 23 Oh, wait. You mean on the last page 24 here?</p>

<p style="text-align: right;">Page 62</p> <p>1 Q. Yes, Doctor.</p> <p>2 A. Oh, I'm sorry.</p> <p>3 I believe the only two that I recall</p> <p>4 are Meghan Carter and Carmen Scott.</p> <p>5 Q. Do you have any recollection of a</p> <p>6 case called Chakalos versus Johnson &amp; Johnson?</p> <p>7 A. I do.</p> <p>8 Q. Did you review Ms. Chakalos's</p> <p>9 medical records?</p> <p>10 A. I did.</p> <p>11 Q. To your knowledge, though, you were</p> <p>12 unaware that you had been designated as a</p> <p>13 testifying expert in that case; is that correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Did you prepare an expert report on</p> <p>16 the Chakalos case?</p> <p>17 MR. TISI: Let me just go</p> <p>18 though this. You can go off the record.</p> <p>19 MR. HEGARTY: Sure. Go off</p> <p>20 the record.</p> <p>21 (Recess: 10:19 a.m. -</p> <p>22 10:28 a.m.)</p> <p>23 MR. HEGARTY: We are back on</p> <p>24 the record.</p>	<p style="text-align: right;">Page 64</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. What was that opinion?</p> <p>4 A. I don't --</p> <p>5 MR. TISI: Objection.</p> <p>6 Whatever -- yeah.</p> <p>7 THE WITNESS: I don't recall.</p> <p>8 MR. TISI: You may answer.</p> <p>9 THE WITNESS: I don't recall.</p> <p>10 MR. TISI: Then that's fine.</p> <p>11 Let me just object because I</p> <p>12 don't know that he knows he was</p> <p>13 designated as an expert. You asked him</p> <p>14 that question, but he -- I would object,</p> <p>15 obviously, to any communications that he</p> <p>16 had with the lawyer on the basis of</p> <p>17 whatever Rule 26 privilege is.</p> <p>18 Because I don't want to put</p> <p>19 words in his mouth, but I believe he</p> <p>20 thought he was a consultant, but go</p> <p>21 ahead.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. This can be a yes or no answer.</p> <p>24 Do you recall if you reviewed any</p>
<p style="text-align: right;">Page 63</p> <p>1 I think there was a discussion</p> <p>2 prior to us starting about making a</p> <p>3 statement as it relates to the New Jersey</p> <p>4 litigation?</p> <p>5 MR. TISI: Yes. First of all,</p> <p>6 we have agreed that an objection by one</p> <p>7 is an objection by all. So that Tracy's</p> <p>8 objections would be preserved.</p> <p>9 And I don't know if there was</p> <p>10 a question pending at the time that we</p> <p>11 took a break.</p> <p>12 MR. HEGARTY: Was there a</p> <p>13 question pending?</p> <p>14 (The reporter read the record</p> <p>15 on page 62 lines 15-16.)</p> <p>16 MR. HEGARTY: Okay. Okay.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. You can answer that question.</p> <p>19 A. Yeah. I don't believe I prepared an</p> <p>20 expert report on that case.</p> <p>21 Q. Did you form an opinion as to the</p> <p>22 cause of Ms. Chakalos's ovarian cancer?</p> <p>23 MR. TISI: That's a yes or no</p> <p>24 question.</p>	<p style="text-align: right;">Page 65</p> <p>1 other patient's medical records when you served in</p> <p>2 this consulting capacity besides Ms. Chakalos's</p> <p>3 medical records?</p> <p>4 A. I believe I did.</p> <p>5 Q. Do you recall the number of other</p> <p>6 women's records you reviewed?</p> <p>7 A. I would say it's no more than two or</p> <p>8 three.</p> <p>9 Q. Was it your understanding when you</p> <p>10 reviewed their records that you had the totality</p> <p>11 of their medical records?</p> <p>12 A. Yes.</p> <p>13 Q. With regard to those review of those</p> <p>14 two or three other women's records, was that also</p> <p>15 back in 2015 and 2016?</p> <p>16 A. It was during that time period, yes.</p> <p>17 Q. Since your consultation back in that</p> <p>18 time period of 2015-2016, have you reviewed the</p> <p>19 medical records of any other woman who you</p> <p>20 understood is claiming ovarian cancer from talcum</p> <p>21 powder use?</p> <p>22 A. Yeah. No.</p> <p>23 Q. Do you still serve in a consulting</p> <p>24 capacity, as you understand it, with the lawyers</p>

<p style="text-align: right;">Page 66</p> <p>1 that are shown in the document I've marked as</p> <p>2 Exhibit Number 4?</p> <p>3 A. Not that I'm aware of.</p> <p>4 Q. When did you understand that</p> <p>5 consulting relationship ended?</p> <p>6 A. At the time of my last submission of</p> <p>7 information. I just never received any further</p> <p>8 communication from them.</p> <p>9 Q. Was the last submission you made</p> <p>10 before the COVID shutdown in 2020?</p> <p>11 A. Oh, well before that. Well before</p> <p>12 that.</p> <p>13 Q. Do you recall how long, how much</p> <p>14 before?</p> <p>15 A. Again, it was all during this period</p> <p>16 of time, 2015 to 2017, something like that. I</p> <p>17 don't believe we shut down on COVID until 2019 was</p> <p>18 it?</p> <p>19 Q. 2020.</p> <p>20 A. 2020, yeah.</p> <p>21 Q. Going back to your initial contact</p> <p>22 with Dr. Rothman about serving as an expert</p> <p>23 witness in this case --</p> <p>24 MR. TISI: Are you done with</p>	<p style="text-align: right;">Page 68</p> <p>1 this case besides in your capacity as a consultant</p> <p>2 and expert witness?</p> <p>3 A. No.</p> <p>4 Q. You know Dr. Daniel Cramer, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Do you know him socially as well as</p> <p>7 professionally?</p> <p>8 A. Not recently.</p> <p>9 Q. Not recently socially?</p> <p>10 A. Correct. When we worked together,</p> <p>11 we ran an office together, and there were times</p> <p>12 when we would have social events with our staff</p> <p>13 and colleagues.</p> <p>14 Q. Are you aware that he has served as</p> <p>15 an expert witness for plaintiffs' lawyers in cases</p> <p>16 involving talcum powder use?</p> <p>17 A. Yes.</p> <p>18 Q. Did you know that because of what he</p> <p>19 told you?</p> <p>20 A. Yes.</p> <p>21 Q. You also know Dr. John Godleski,</p> <p>22 correct?</p> <p>23 A. The name doesn't ring a bell.</p> <p>24 Q. I'm going to read you a list of</p>
<p style="text-align: right;">Page 67</p> <p>1 this?</p> <p>2 MR. HEGARTY: I'm done with</p> <p>3 that.</p> <p>4 THE WITNESS: Should I give</p> <p>5 this back to you?</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. You can keep those over on that</p> <p>8 side.</p> <p>9 MR. TISI: Let me kind of keep</p> <p>10 track of your exhibits.</p> <p>11 THE WITNESS: Okay.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Going back to your initial contact</p> <p>14 with Dr. Rothman about serving as an expert</p> <p>15 witness in this litigation, did he encourage you</p> <p>16 to serve as an expert witness?</p> <p>17 A. No.</p> <p>18 Q. How did -- let me strike that.</p> <p>19 Apart from anything that you were</p> <p>20 told by attorneys, do you know how Dr. Rothman</p> <p>21 came to be contacted in the first place?</p> <p>22 A. No.</p> <p>23 Q. Do you have any social or business</p> <p>24 relationship to any lawyer for the plaintiffs in</p>	<p style="text-align: right;">Page 69</p> <p>1 other plaintiffs' experts that have been</p> <p>2 designated in this case. Tell me if you know them</p> <p>3 personally.</p> <p>4 Dr. McTiernan?</p> <p>5 A. I know of her, and she and I trained</p> <p>6 at the same time as the University of Washington.</p> <p>7 Q. Do you know Dr. Siemiatycki?</p> <p>8 A. I do not know him. I know of him.</p> <p>9 Q. Do you know Dr. Moorman?</p> <p>10 A. I do not know her.</p> <p>11 Q. Do you know Dr. Clarke-Pearson?</p> <p>12 A. No.</p> <p>13 Q. He's a gynecologic oncologist.</p> <p>14 A. No.</p> <p>15 Q. Do you know Dr. Cote?</p> <p>16 A. No.</p> <p>17 Q. Do you know Dr. Sonal Singh?</p> <p>18 A. No.</p> <p>19 Q. Do you know Dr. Smith-Bindman?</p> <p>20 A. No.</p> <p>21 Q. Do you Dr. Roberta Ness?</p> <p>22 A. Yes.</p> <p>23 Q. Do you know her personally and</p> <p>24 professionally?</p>

<p style="text-align: right;">Page 70</p> <p>1 A. I know her professionally. We sat 2 on committees. We have attended the same meetings 3 often. And so when I see her in those capacity, 4 we're very cordial professionally, but never had 5 any kind of social event with her. 6 Q. Do you know that Dr. Ness serves as 7 an expert witness for plaintiffs in talcum powder 8 cases? 9 A. Yes. 10 Q. How do you know that? 11 A. I was told. 12 Q. Were you told that by Dr. Ness? 13 A. No. 14 Q. Were you told that by attorneys in 15 this case? 16 A. Yes. 17 Q. Have you ever talked to -- 18 MR. TISI: I let that one slip 19 by the way. Go ahead. 20 BY MR. HEGARTY: 21 Q. Have you ever talked to Dr. Ness 22 about her or you serving as an expert witness in 23 cases involving talcum powder use? 24 A. No.</p>	<p style="text-align: right;">Page 72</p> <p>1 have been involved, and my main contact is with 2 Mr. Tisi and Ms. Parfitt. 3 Q. During that initial discussion you 4 had with Dr. Rothman, did you agree to serve as or 5 participate as an expert witness in this 6 litigation? 7 MR. TISI: Objection. 8 Mischaracterizes his prior testimony. He 9 said he was requested to write a report. 10 BY MR. HEGARTY: 11 Q. You can answer. 12 A. No, I was not asked by Dr. Rothman 13 to serve as an expert witness. 14 Q. At what point in time did you agree 15 relative to your invoice dates to serve as an 16 expert witness for plaintiffs in this litigation? 17 A. After Dr. Rothman and I had 18 completed our report. 19 Q. What -- when from the invoices we 20 looked at did you complete your report? 21 A. Can I refer back to the invoices? 22 Q. Sure. 23 MR. TISI: I got them right 24 here. I've given you my copy but...</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. Have you ever talked to Dr. Cramer 2 about his experiences in serving as an expert 3 witness in talcum powder cases? 4 A. No. 5 Q. Has Dr. Cramer or Dr. Ness or any 6 other colleague of yours, or someone who's in the 7 same profession, ever encouraged you to 8 participate in this litigation as an expert 9 witness? 10 A. No. 11 Q. Did you consult with anyone outside 12 of attorneys prior to agreeing to serve as an 13 expert witness in this litigation? 14 A. Only to the extent of knowing what I 15 should charge, as I indicated before. 16 Q. You mentioned Mr. Tisi and you 17 mentioned Ms. Parfitt. You mentioned perhaps 18 Ms. O'Dell. 19 Do you recall the names of any other 20 lawyers that you have worked with as part of your 21 involvement in the talcum powder litigation that 22 we're here to talk about today? 23 A. Only those that are aligned with 24 this group of attorneys here. There are more that</p>	<p style="text-align: right;">Page 73</p> <p>1 THE WITNESS: No, no. That's 2 okay. 3 (Reviews document.) 4 I would -- yeah, I would say 5 by the end of November 2023. 6 BY MR. HEGARTY: 7 Q. How was it that it was till the end 8 of November 2023 that you agreed to serve as an 9 expert witness for plaintiffs in this litigation? 10 A. Because that's when we completed the 11 report and it was I was asked to be in that 12 capacity. 13 Q. What did you understand your work to 14 be prior to being asked to serve as an expert 15 witness in this litigation? 16 A. Prior to being asked is to prepare a 17 report on the state of the evidence. 18 Q. What did you understand your 19 capacity to be in preserving -- in preparing that 20 report? As a consultant, as an expert, retained 21 expert witness, or something else? 22 A. I didn't really think of it in that 23 way. I was asked to prepare the report. I was 24 interested in doing it and -- but I didn't think</p>



<p style="text-align: right;">Page 74</p> <p>1 about how I would be classified one way or 2 another. 3 Q. Now, with regard to what we've been 4 talking about here today and recently in just the 5 last few moments, you did review materials that 6 plaintiffs' counsel provided and that you obtained 7 yourself and prepared an expert report, correct? 8 A. That's correct. 9 Q. That expert report is dated 10 November 15, 2023? 11 A. It's dated November on my copy. 12 Q. I'm sorry. I may have misspoke. 13 Your expert report is dated 14 November 15, 2023? 15 A. Again, on my copy it just says 16 November 2023. 17 Q. Is there a date at the end with your 18 signature? 19 A. Ah. Quite likely. Let me see. 20 MR. TISI: I think that was 21 the date it was submitted. 22 THE WITNESS: No, there isn't 23 a date. 24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 76</p> <p>1 asked first by Mr. Tisi and others to be involved. 2 MR. HEGARTY: We'll go ahead 3 for purposes of the record to mark your 4 report. We are on Exhibit Number 6. So 5 I'm going to mark -- I'm sorry. Exhibit 6 Number 5. We're going to mark your 7 report -- I want to make clear. 8 I'm on Exhibit Number 5? 9 MS. PARFITT: I have 5. 4 was 10 the designation. 11 MR. HEGARTY: Okay. I'm 12 marking as Exhibit Number 5 a copy of the 13 expert report we've been provided for you 14 for this case. 15 (Document marked for 16 identification as Harlow Exhibit 5.) 17 BY MR. HEGARTY: 18 Q. It does have a cover page which you 19 might not have seen before. 20 A. It also looks a lot thicker. 21 MR. TISI: Was Number 3 his 22 CV? 23 THE WITNESS: Oh, this is -- 24 it has my CV in here as well.</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. You were compensated for the work 2 you did on your expert report; is that correct? 3 A. That's correct. 4 Q. You wrote your expert report with 5 Dr. Rothman, correct? 6 A. Yes. 7 Q. Are you aware that plaintiffs' 8 counsel in this case has withdrawn Dr. Rothman as 9 an expert? 10 A. Yes. 11 Q. Did you discuss Dr. Rothman's 12 withdrawal with Dr. Rothman? 13 A. No. 14 Q. Apart from any discussions you had 15 with counsel for plaintiffs, do you know why he 16 has been withdrawn as an expert witness? 17 A. I do not. 18 Q. Do you know that your report is the 19 only coauthored report in this litigation? 20 A. I believe I was told that. 21 Q. Why did you prepare a coauthored 22 report? 23 A. Because Dr. Rothman asked for me to 24 do it collaboratively with him because he had been</p>	<p style="text-align: right;">Page 77</p> <p>1 MS. PARFITT: Number 3 is his 2 CV. CV is separate. 3 BY MR. HEGARTY: 4 Q. So Dr. Harlow -- I'm sorry, 5 Dr. Rothman -- Harlow, with regard to your expert 6 report that we're looking at, Exhibit Number 5 -- 7 A. Oh, right. Yeah. 8 Q. -- is the first part of these pages 9 specifically 1 through 24 your expert report? 10 A. Yes, it is. 11 Q. It also includes as exhibits your 12 curriculum vitae, the curriculum vitae of -- and 13 the curriculum vitae of Dr. Harlow, as well as a 14 list at the end which is a Materials Considered 15 list, Exhibit C. 16 Do you see that? 17 A. I -- I believe I do. Oh, actually 18 -- oh, yeah, Exhibit C, Materials Considered. 19 Yes. Uh-huh. 20 Q. How was the work on your report 21 divided between you and Dr. Rothman? 22 A. It was collaborative. 23 Q. Did you and/or Dr. Rothman write 24 particular sections of your report?</p>

<p style="text-align: right;">Page 78</p> <p>1 A. There were some sections we wrote 2 together. There were some sections that 3 Dr. Rothman took the lead on. There were some 4 sessions that I took the lead on. 5 Q. Which sections did you take the lead 6 on and which sections did Dr. Rothman take the 7 lead on? 8 A. Dr. Rothman clarified the 9 methodologic approach that we did, I wrote the 10 initial drafts of the reviews of most of the 11 scientific literature that is documented in there, 12 and then together we wrote the Executive Summary 13 and I believe our concluding thoughts. 14 But it was an iterative process 15 where we were back and forth on modifying each 16 other's sections that we had initially written. 17 Q. So did you and Dr. Rothman write 18 initial sections separate and then combine them? 19 A. We would write our sections and we 20 would discuss it. And as I indicated on my 21 invoices, when we were meeting, we would be 22 modifying our sections based on joint input on the 23 appropriate wording to be used. 24 Q. Do the invoices we looked at reflect</p>	<p style="text-align: right;">Page 80</p> <p>1 A. Well, I got to know him better when 2 I came to Boston University. I, obviously, have 3 known of him and I believe I had met him once. I 4 met him at scientific meetings. And he was a very 5 close friend and colleague of my mentor at the 6 University of Washington, Dr. Noel Weiss, who I 7 coauthored one of my papers with. 8 Q. Do you know Dr. Rothman socially as 9 well as professionally? 10 A. Now I do. 11 Q. Have you read all of his 12 publications? 13 A. What, 600 or so? (Laugh). No, I 14 can't believe -- I don't believe I've read all of 15 him, but I've read certainly the seminal 16 publications that he's written. 17 Q. Have you read any of his textbooks? 18 A. I use his textbook. 19 Q. Which textbook do you use? 20 A. "Modern Epidemiology." 21 Q. Are all the hours you have spent 22 working on this litigation reflected in the 23 invoices we marked as an exhibit and then what you 24 told me what you have done since that time?</p>
<p style="text-align: right;">Page 79</p> <p>1 the hours that you spent with Dr. Rothman in 2 preparing this report? 3 A. I believe it does. 4 Q. Does it show all the hours that you 5 spent with Dr. Rothman in writing your report? 6 A. Yes. 7 Q. Does it also reflect all the hours 8 you spent working on your report? 9 A. I believe it does. 10 Q. In the process of preparing your 11 report, did you communicate with Dr. Rothman by 12 e-mail? 13 A. Yes. 14 Q. Do you still have those e-mails? 15 A. No. 16 Q. With regard to the final report, did 17 you read and approve each statement in the report? 18 A. Yes. 19 Q. Was there any disagreement on 20 statements as you were preparing the report? 21 A. I wouldn't say we had disagreements. 22 I think we -- we came to consensus on the 23 appropriate wording. 24 Q. How long have you known Dr. Rothman?</p>	<p style="text-align: right;">Page 81</p> <p>1 A. That's correct. 2 Q. Have you done any other work on this 3 litigation that's not reflected in your invoices 4 or what you told me about so far today? 5 A. No. 6 Q. Looking at your report over on page 7 20, you state at the bottom that: 8 "It is our opinion that talcum 9 powder products, including Johnson's Baby Powder 10 and Shower to Shower, applied to the genital area 11 of women, can cause ovarian cancer." 12 Do you see where I'm reading? 13 A. Yes, I do. 14 Q. Does your opinion apply to corn 15 starch products? 16 A. No, it does not. 17 Q. Does your opinion apply to body 18 powders generally? 19 A. Only to the extent that they include 20 talc. 21 Q. With regard to the opinion statement 22 that I just read at the bottom of page 20 -- 23 A. Uh-huh. 24 Q. -- you have never made that</p>



<p style="text-align: right;">Page 82</p> <p>1 statement in any published peer-reviewed 2 publication, correct? 3 A. I have not. Not -- not the word 4 "cause." 5 Q. You have never made the statement 6 that I just read to you in anything you have 7 written before November 2023, correct? 8 A. In any public statement, no. 9 Q. Have you made this statement in 10 anything other than this report since November 11 2023? 12 A. No. 13 Q. On page 2 of your report -- 14 A. Uh-huh. 15 Q. -- you identify your publications on 16 talc use and ovarian cancer, correct? 17 A. Yes. 18 Q. There are four published articles 19 and one letter to the editor? 20 A. Correct. 21 Q. Your last published peer-reviewed 22 article was in 1999, 25 years ago, right? 23 A. Yes, but I don't know to what extent 24 the editors at JAMA peer review letters to the</p>	<p style="text-align: right;">Page 84</p> <p>1 A. I'm sorry. Under the what section? 2 Q. The abstract section. 3 A. Oh, the abstract. Yes, yes, yes. 4 Q. The end of the first paragraph below 5 that. 6 A. Yes. 7 Q. You note in this article that: 8 "Despite this consistency, the 9 association is still viewed with skepticism based 10 upon weak odds ratios, poor dose-response 11 relationships and an incomplete understanding of 12 the biological mechanism by which talc might lead 13 to ovarian cancer." 14 Do you see where I'm reading? 15 A. No, I'm not sure I do. 16 Q. (Indicates). 17 A. Oh, oh, oh. It's not in the 18 abstract. 19 MR. TISI: It's not in the 20 abstract. You said the abstract. 21 BY MR. HEGARTY: 22 Q. I said the paragraph below the 23 abstract. 24 A. Oh, I'm sorry. I'm sorry.</p>
<p style="text-align: right;">Page 83</p> <p>1 editor. 2 Q. Fair. 3 You don't know one way or the other? 4 A. I don't know one way or the other. 5 Q. You do not state in any of your 6 published articles that talc use can cause ovarian 7 cancer, correct? 8 A. I don't recall that I use that 9 particular term, but I would have to look and see. 10 Q. With regard to your 1999 11 publication, I'm going to show that to you. 12 A. Yes. 13 MR. HEGARTY: I have marked it 14 as Exhibit Number 6. 15 THE WITNESS: Yes. 16 (Document marked for 17 identification as Harlow Exhibit 6.) 18 BY MR. HEGARTY: 19 Q. Is Exhibit Number 6 your 1999 20 publication? 21 A. That's correct. 22 Q. If you can look at the first 23 paragraph under the abstract section on page 1, 24 you wrote --</p>	<p style="text-align: right;">Page 85</p> <p>1 Okay. 2 Q. Do you see where I read in the -- 3 A. Could you please reread it so I can 4 see what it is? 5 Q. The sentence is. 6 "Despite this consistency, the 7 association is still viewed with skepticism -- 8 A. Yes. 9 Q. -- based upon weak odds ratios, poor 10 dose-response relationships and an incomplete 11 understanding of biological mechanism by which 12 talc might lead to ovarian cancer." 13 Those were true statements in 1999 14 when you published this article, correct? 15 A. Yes. Yes, there was definitely -- 16 there was skepticism. 17 Q. Please turn over to page 354 of this 18 article, bottom left-hand paragraph. 19 A. Yes. 20 Q. You wrote: 21 "Despite the consistency noted 22 above, the relatively weak odds ratios observed 23 could reflect potential biases, especially recall 24 and confounding. Recall bias is possible because</p>

<p style="text-align: right;">Page 86</p> <p>1 talc exposure in these studies is based on 2 personal recollection." 3 That's a true statement, correct? 4 A. Except that if you look at the 5 sentence following that, it seems that recall bias 6 seems more likely to affect exposures that have 7 occurred over a short period of time. 8 Q. As far as the sentence I just read 9 to you, though, you stand by that sentence, 10 correct? 11 A. I stand by recall bias is a possible 12 -- could have a possible effect in those who have 13 used it sporadically over their lifetime. 14 Q. But in terms of all the statements 15 in this article, you still stand by them, correct? 16 A. Yes, I believe so. I mean, yes, I 17 stand by everything I've written. 18 Q. Please turn over to page 355. 19 A. Uh-huh. 20 Q. Left-hand side, end of the paragraph 21 -- end of the left-hand side. 22 MR. TISI: Let me get there, 23 Mark. 24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 88</p> <p>1 dose response. 2 BY MR. HEGARTY: 3 Q. What I read to you was a true 4 statement as of the time you published this 5 article, correct? 6 A. Yes. 7 Q. IARC published its monograph 8 regarding talc use -- 9 MR. TISI: Are you done with 10 this? 11 MR. HEGARTY: I'm done with it 12 for now. 13 MR. TISI: Okay. 14 BY MR. HEGARTY: 15 Q. IARC published its monograph 16 regarding talc use and ovarian cancer in 2010 17 where it designated talc as to be possibly 18 carcinogenic. 19 Did you read that monograph when it 20 came out? 21 A. I can't say that I read it when it 22 came out. 23 Q. Do you recall when it was when you 24 did read that IARC Monograph, if you did?</p>
<p style="text-align: right;">Page 87</p> <p>1 Q. That paragraph reads: 2 "The most obvious weakness in the 3 argument for biologic credibility of the talc and 4 ovarian cancer association is the lack of a clear 5 dose response. Most talc and ovarian cancer 6 studies that have addressed dose response, 7 including this one, have failed to demonstrate 8 consistent dose response relationships with 9 measures of the intensity of the exposure, 10 especially when the trend is examined among users 11 only." 12 Do you stand by that statement? 13 MR. TISI: Objection. 14 Incomplete based upon the entirety of the 15 article. 16 Go ahead. 17 THE WITNESS: Yeah. Again, I 18 am -- I am -- this paragraph reflects the 19 fact that very few articles have had the 20 capacity to be able to accurately and 21 appropriately have the data to be able to 22 show the dose response. 23 However, this particular paper 24 does have data to be able to show the</p>	<p style="text-align: right;">Page 89</p> <p>1 A. I looked at that monograph and other 2 IARC statements during the process of reviewing 3 the evidence. 4 Q. "During the process of reviewing the 5 evidence." 6 Are you talking about during the 7 process of reviewing the evidence in connection 8 with preparing your expert report? 9 A. Yes. 10 Q. Prior to you starting to work on 11 your expert report, had you ever reviewed the 2010 12 IARC Monograph on talc? 13 A. I don't believe I did. 14 Q. Did you come to the opinion in your 15 report that talc applied to the genital area can 16 cause ovarian cancer before being contacted by 17 plaintiffs' counsel back in 2023? 18 A. I have always in my written 19 publications believed that the association with 20 respect to genital application of talc and its 21 risk of ovarian cancer was a true association. 22 Q. My question, though, is a little bit 23 different. 24 My question is: With regard to the</p>

<p style="text-align: right;">Page 90</p> <p>1 opinion that you've said in your report that talc  2 applied to the genital area can cause ovarian  3 cancer, did you come to that opinion prior to  4 being contacted by plaintiffs' counsel about  5 serving as an expert witness in this litigation?  6 A. I believe in my -- in my 1992  7 article, I basically indicated that I believed  8 that about 10 percent of the incidence of ovarian  9 cancer could be or was attributable to talc  10 exposure.  11 Q. My question still is a little  12 different than what you're answering.  13 You just -- you told me about what  14 you believed as to the association being a true  15 association. You told me what you wrote in your  16 1992 article about 10 percent of cases  17 involving --  18 A. 10 percent of the incidence.  19 Q. 10 percent of the incidence.  20 My question is specifically as to  21 the causal statement you made in your expert  22 report.  23 When did you come to that causal  24 opinion?</p>	<p style="text-align: right;">Page 92</p> <p>1 A. I believed in the research that I  2 had done and the associations that I observed as  3 being -- as not being explained by biases to my --  4 based on my evaluation.  5 I certainly -- yeah.  6 Q. Go ahead.  7 Have you reviewed the transcript of  8 the proceedings?  9 A. I have. I have.  10 Q. When did you review the transcript  11 of the proceedings?  12 A. Recently, actually.  13 MR. HEGARTY: I'm going to  14 mark as the next exhibit, Exhibit  15 Number 7, the transcript of the FDA  16 workshop proceeding.  17 (Document marked for  18 identification as Harlow Exhibit 7.)  19 THE WITNESS: Yep.  20 BY MR. HEGARTY:  21 Q. Is the transcript that I marked as  22 Exhibit Number 7 what you reviewed recently?  23 A. Yes.  24 Q. Please turn over to page 272. They</p>
<p style="text-align: right;">Page 91</p> <p>1 A. I came to that causal opinion in  2 doing this report.  3 Q. Now, as you mentioned a short time  4 ago, you attended the 1994 workshop on talc that  5 was cosponsored by FDA, correct?  6 A. Yes.  7 Q. In fact, you spoke at that  8 conference?  9 A. Yes.  10 Q. Do you still have the slides or  11 materials you used at that conference?  12 A. No. I'm not sure they even had  13 slides. It may have been transparencies. I don't  14 remember.  15 Q. You did not tell the audience that  16 talc use in the genital area can cause ovarian  17 cancer, correct?  18 A. I did not use that term.  19 Q. And you did not believe that at the  20 time, correct?  21 A. I did not use that term.  22 Q. Well, did you believe at the time  23 that you presented to the FDA workshop that talc  24 use in the genital area can cause ovarian cancer?</p>	<p style="text-align: right;">Page 93</p> <p>1 are numbered at the top.  2 A. Yep.  3 I'm going to take the clip off. If  4 that's okay?  5 Q. That is fine.  6 A. Okay.  7 Q. In the last paragraph on 272, you  8 stated at that conference:  9 "In summary, these results suggest  10 that if an association of talc exposure and  11 ovarian cancer truly exists, it is probably weak  12 and does not explain a large proportion of the  13 overall incidence of ovarian cancer."  14 That's what you said at that  15 conference?  16 A. That's right, and that's what I just  17 said to you as well.  18 Q. That's what you believed at the  19 time?  20 A. Yes.  21 Q. That was a true statement, correct?  22 A. Yes.  23 MR. HEGARTY: You can put that  24 document aside.</p>

<p style="text-align: right;">Page 94</p> <p>1 The next document I'm going to</p> <p>2 show you, which I'm marking as Exhibit</p> <p>3 Number 8, is the publication by Carr that</p> <p>4 came out of that FDA workshop.</p> <p>5 (Document marked for</p> <p>6 identification as Harlow Exhibit 8.)</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Have you seen the publication I</p> <p>9 marked as Exhibit Number 8 before today?</p> <p>10 A. Oh, yes.</p> <p>11 Q. And did you review that recently?</p> <p>12 A. Yes.</p> <p>13 Q. It shows on page 2 that you were a</p> <p>14 participant?</p> <p>15 A. That's correct.</p> <p>16 Q. Please turn to page 214 of the Carr</p> <p>17 paper.</p> <p>18 First of all, before we go there.</p> <p>19 Did you review the Carr paper when</p> <p>20 it came out back in 1995?</p> <p>21 A. I did not -- I don't recall. I did</p> <p>22 not -- I was not involved in the preparation or</p> <p>23 review of this. I might have seen it before it</p> <p>24 came in print. I just -- I don't recall.</p>	<p style="text-align: right;">Page 96</p> <p>1 That was a statement made at the</p> <p>2 conference.</p> <p>3 Are you aware of that?</p> <p>4 A. I'm not aware of that.</p> <p>5 Q. Turn over to page 215, the next</p> <p>6 page.</p> <p>7 A. Uh-huh.</p> <p>8 Q. Look at the very bottom of the</p> <p>9 left-hand column carrying over to the right-hand</p> <p>10 column.</p> <p>11 A. Uh-huh.</p> <p>12 Q. The sentence at the very bottom</p> <p>13 reads:</p> <p>14 "Following the many issues raised by</p> <p>15 all presenters, the ensuing discussion generally</p> <p>16 agreed that while some weak association between</p> <p>17 talc exposure and ovarian tumors has been</p> <p>18 reported, it was not sufficient warning for</p> <p>19 concern."</p> <p>20 First of all, did I read it</p> <p>21 correctly?</p> <p>22 A. You did read it correctly.</p> <p>23 Q. Do you dispute that statement?</p> <p>24 A. Yes, I do.</p>
<p style="text-align: right;">Page 95</p> <p>1 Q. Had you read it in some context</p> <p>2 prior to being contacted by plaintiffs' counsel in</p> <p>3 this litigation?</p> <p>4 A. Oh, prior to this litigation?</p> <p>5 Q. Yes, sir.</p> <p>6 A. I'm sure I did back in the '90s, but</p> <p>7 not since then.</p> <p>8 Q. And in looking at page 214 --</p> <p>9 A. Yes.</p> <p>10 Q. -- in the lower right-hand corner,</p> <p>11 if you look sort of in the middle of that very</p> <p>12 last paragraph, the sentence beginning "To</p> <p>13 reasonable people."</p> <p>14 Do you see that sentence?</p> <p>15 A. In which paragraph?</p> <p>16 Q. (Indicates).</p> <p>17 A. Oh, right around there.</p> <p>18 Yes, I see it. Uh-huh.</p> <p>19 Q. That article reads:</p> <p>20 "To reasonable people -- even armed</p> <p>21 with reasonable concern for prudence -- these</p> <p>22 clues suggest that the probability of human risk</p> <p>23 is likely nonexistent under customary conditions</p> <p>24 of use."</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Back when you reviewed Carr, did you</p> <p>2 write a letter to the editor or contact the</p> <p>3 authors -- let me start over again.</p> <p>4 Back when you reviewed the Carr</p> <p>5 study back in the 1990s, did you contact Carr or</p> <p>6 any of those involved in this publication and</p> <p>7 express concern about any of the language used in</p> <p>8 the article?</p> <p>9 A. No.</p> <p>10 MR. TISI: Objection. Wait.</p> <p>11 Let me place an objection to the</p> <p>12 characterization of this article as a</p> <p>13 study. It's not a study.</p> <p>14 You may answer.</p> <p>15 THE WITNESS: No. Instead, I</p> <p>16 wrote an entire review article that was</p> <p>17 published in that issue, which summarized</p> <p>18 what we had presented at the conference.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. Have you ever in any published --</p> <p>21 any publication of yours specifically addressed</p> <p>22 any of the statements in the Carr article?</p> <p>23 A. No.</p> <p>24 Q. Have you publicly in any forum,</p>

<p style="text-align: right;">Page 98</p> <p>1 whether published or otherwise, taken issue with  2 any of the statements contained in the Carr  3 article, including the statements I read to you?  4 A. No, not in any public -- no, not  5 publicly at all.  6 MR. HEGARTY: You can put that  7 document aside for the moment.  8 The next document I want to  9 talk to you about, which I'll mark as  10 Exhibit Number 9, is Dr. Rothman et al.'s  11 document "Interpretation of Epidemiologic  12 Studies on Talc and Ovarian Cancer."  13 (Document marked for  14 identification as Harlow Exhibit 9.)  15 THE WITNESS: Uh-huh.  16 MR. TISI: Are you talking  17 about --  18 MR. HEGARTY: The one I just  19 handed to you.  20 MR. TISI: Okay.  21 THE WITNESS: Uh-huh.  22 BY MR. HEGARTY:  23 Q. When did you first see Exhibit  24 Number 9?</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. Does he stand by what he wrote back  2 in 2000?  3 A. He stands by what he signed his name  4 to in the report that we wrote together.  5 Q. My question, though, is: Does he  6 stand by, from what he has told you, what I marked  7 as Exhibit Number 9?  8 MS. PARFITT: Objection.  9 THE WITNESS: I have no idea  10 whether he does or not.  11 BY MR. HEGARTY:  12 Q. Turning to page 2, in the  13 "Introduction" section, Dr. Rothman wrote that he  14 analyzed 23 case-control studies involving talc  15 and ovarian cancer.  16 These included your studies as well,  17 correct?  18 A. Uh-huh.  19 Q. Yes, sir?  20 A. Yes.  21 MR. TISI: Say "yes."  22 THE WITNESS: I'm sorry.  23 Yes.  24 BY MR. HEGARTY:</p>
<p style="text-align: right;">Page 99</p> <p>1 A. I first saw it after I had started  2 doing work in preparation for our report that  3 Dr. Rothman and I did.  4 Q. The conclusion of this analysis is  5 set on page 1.  6 A. Yes.  7 Q. And that conclusion --  8 A. Oh, the Executive Summary?  9 Q. In the Executive Summary.  10 A. Yep.  11 Q. At the end, it says:  12 "Based on these considerations, we  13 suggest that the evidence to date does not  14 indicate that talc can be 'reasonably anticipated  15 to be a human carcinogen.'  16 Did I read that correctly?  17 A. Yes, you did.  18 Q. And you did not cite that conclusion  19 anywhere in your report, correct?  20 A. No, because I don't believe it to be  21 true.  22 Q. Did you talk with Dr. Rothman about  23 this analysis?  24 A. Yes.</p>	<p style="text-align: right;">Page 101</p> <p>1 Q. The "Introduction" section above  2 Figure 1, just above Figure 1 --  3 A. Yes.  4 Q. -- states or notes that the relative  5 risk concluded from that review is 1.31. That is  6 characterized or called as a "slight positive  7 association."  8 Do you see where I'm reading?  9 A. Yes.  10 Q. Do you agree that the relative risk  11 that Dr. Rothman reported of 1.31 was a slight  12 positive association?  13 A. It's a positive association.  14 Q. You would not characterize it as  15 slight?  16 A. No. That's a term that we would not  17 normally use.  18 Q. In your report for this litigation,  19 you did not do a strength of association analysis,  20 correct?  21 MR. TISI: Objection.  22 THE WITNESS: I'm not sure  23 what you mean by a "strength of  24 association analysis."</p>



<p style="text-align: right;">Page 102</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Let me ask in a different way.</p> <p>3 Do you state anywhere in your report</p> <p>4 that the relative risks or odds ratios reported</p> <p>5 for talc use and ovarian cancer are strong?</p> <p>6 A. I don't believe we used "strong" as</p> <p>7 a word. I believe we used "consistently seen"</p> <p>8 across multiple studies and --</p> <p>9 Q. Did you -- I'm sorry. Go ahead.</p> <p>10 A. -- and meta-analyses show a</p> <p>11 consistent association with narrow confidence</p> <p>12 intervals.</p> <p>13 Q. Is it your opinion in this</p> <p>14 litigation that the relative risks and odds ratios</p> <p>15 that are reported for talc use and ovarian cancer</p> <p>16 are strong?</p> <p>17 MR. TISI: Objection.</p> <p>18 THE WITNESS: Yeah. I would</p> <p>19 say they are clinically relevant and</p> <p>20 important.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. Have you ever characterized in any</p> <p>23 publication of yours relative risks in the range</p> <p>24 of 1.2, 1.3, 1.4 as weak?</p>	<p style="text-align: right;">Page 104</p> <p>1 You actually refer to the 1.31</p> <p>2 finding from Dr. Rothman's 2000 study, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. And you actually show --</p> <p>5 A. And we cite it.</p> <p>6 Q. And you cite to it?</p> <p>7 A. Yes.</p> <p>8 Q. You show Figure 1 from the 2000</p> <p>9 paper of Dr. Rothman?</p> <p>10 A. That's correct.</p> <p>11 Q. You note at the bottom of page 7</p> <p>12 that:</p> <p>13 As regards to the 1.31 estimated</p> <p>14 risk ratio that if valid, it would apply a 31</p> <p>15 percent greater risk of ovarian cancer among talc</p> <p>16 users.</p> <p>17 Correct?</p> <p>18 A. That's correct.</p> <p>19 Q. Now, Dr. Rothman in this, in his</p> <p>20 analysis in Exhibit Number 9 --</p> <p>21 A. Yes.</p> <p>22 Q. -- his 2000 analysis, did not</p> <p>23 believe it was valid, correct?</p> <p>24 MR. TISI: Objection.</p>
<p style="text-align: right;">Page 103</p> <p>1 A. I'm sure I have.</p> <p>2 Q. In fact, we looked at your 1999</p> <p>3 publication where you characterized the reported</p> <p>4 relative risks at the time as weak odds ratios,</p> <p>5 correct?</p> <p>6 A. That's correct.</p> <p>7 Q. Back in 1999, based on the odds</p> <p>8 ratios you had reviewed at the time, you</p> <p>9 considered those to be weak odds ratios, correct?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: No. Well, weak</p> <p>12 odds ratios merely means that -- it</p> <p>13 doesn't mean that it's clinically</p> <p>14 important. It means that it's not 3.0,</p> <p>15 4.0, 5.0. It happened to be around 1.3,</p> <p>16 1.4.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Looking at page 2 of your report.</p> <p>19 A. Of my report?</p> <p>20 Q. Of your report.</p> <p>21 I'm sorry. It is -- it is page 7.</p> <p>22 A. Yes.</p> <p>23 Q. You state at the bottom -- or, first</p> <p>24 of all, before I go there.</p>	<p style="text-align: right;">Page 105</p> <p>1 THE WITNESS: I don't know</p> <p>2 whether he believed it was valid or not.</p> <p>3 He -- well, I'm looking for where he</p> <p>4 might have -- where he specifically said</p> <p>5 that.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Well, based on the conclusion --</p> <p>8 A. Yeah.</p> <p>9 Q. -- at the bottom of the Executive</p> <p>10 Summary, wouldn't you agree that he did not</p> <p>11 believe that 1.31 relative risk --</p> <p>12 MR. TISI: Objection.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. -- or risk ratio -- let me finish my</p> <p>15 question -- risk ratio was valid?</p> <p>16 MR. TISI: Object. Let me</p> <p>17 just object.</p> <p>18 You referred to the Executive</p> <p>19 Summary as a conclusion. As you know,</p> <p>20 counsel, there is actually a Conclusion</p> <p>21 in the report that is not the Executive</p> <p>22 Summary.</p> <p>23 So if you want him to look at</p> <p>24 the Conclusion, look at the Conclusion,</p>

<p style="text-align: right;">Page 106</p> <p>1 but don't characterize the Executive  2 Summary as a conclusion.  3 BY MR. HEGARTY:  4 Q. You can answer.  5 A. I guess I would agree with counsel  6 that his ultimate opinion came in the summary of  7 the -- of the report.  8 Q. Well, the conclusion --  9 A. Let's look at that.  10 Q. -- on page 8, the very bottom it  11 says:  12 "Based on these considerations" --  13 referring to what he described above -- again,  14 this is page 8.  15 A. Oh, page 8.  16 Q. The "Conclusion" section.  17 A. Yeah. Hold on. Yes. Uh-huh.  18 Q. He writes:  19 "Based on these considerations, we  20 suggest that the evidence to date does not  21 indicate that talc can be 'reasonably anticipated  22 to be a human carcinogen.'"  23 Correct?  24 MR. TISI: Please, you're free</p>	<p style="text-align: right;">Page 108</p> <p>1 MR. TISI: Objection.  2 BY MR. HEGARTY:  3 Q. You would not have wrote -- you  4 would not have authored the statements contained  5 in Dr. Rothman's 2000 report?  6 A. Absolutely not. Especially given  7 that he specifically stated that there was no  8 biological plausibly -- plausible explanation for  9 it, and there was ample evidence at that time of  10 this report.  11 Q. Did Dr. Rothman tell you what he  12 thought had changed since 2000 --  13 A. No.  14 Q. -- that would change his opinions?  15 A. No.  16 Q. If you look over on page 3?  17 A. Of his report?  18 Q. Of his 2000 publication.  19 A. 2000 report. Okay. Hold on.  20 MR. TISI: Objection to  21 calling it a publication.  22 THE WITNESS: Okay.  23 BY MR. HEGARTY:  24 Q. Look under the section "Issues</p>
<p style="text-align: right;">Page 107</p> <p>1 to read the entire Conclusion.  2 THE WITNESS: Yeah, yeah.  3 (Reviews document.)  4 Yes, he states that.  5 BY MR. HEGARTY:  6 Q. So do you disagree that Dr. Rothman  7 back in 2000 did not find valid that the -- that  8 there was a 31 percent greater risk for ovarian  9 cancer among talc users?  10 MR. TISI: Objection.  11 THE WITNESS: I believe --  12 MR. TISI: That misstates --  13 states what he said.  14 Go ahead.  15 BY MR. HEGARTY:  16 Q. You can answer.  17 A. Well, I believe that's what he  18 thought at the time. Obviously, given that he  19 coauthored my report, he does not believe that  20 now.  21 Q. When you read the 2000 summary, did  22 you agree that it was accurate at the time it was  23 prepared?  24 A. No.</p>	<p style="text-align: right;">Page 109</p> <p>1 Affecting Causal Inference" section.  2 Do you see that?  3 A. Yes.  4 Q. This describes a methodology  5 Dr. Rothman performed back in 2000, correct?  6 A. Yes.  7 Q. As to dose --  8 MR. TISI: Actually, if you're  9 going to refer to the section and ask you  10 about the methodology, please read it,  11 sir.  12 THE WITNESS: Yeah, yeah.  13 BY MR. HEGARTY:  14 Q. As to dose response --  15 MR. TISI: Give him a chance  16 to read it, Mark.  17 MR. HEGARTY: Okay, but he  18 didn't ask he needed to read it.  19 THE WITNESS: No, I don't.  20 You can ask the question.  21 MR. TISI: You can't -- ask  22 the question, but he does need to read it  23 if you want to ask him about the  24 methodology.</p>



<p style="text-align: right;">Page 110</p> <p>1 MR. HEGARTY: Chris, I think</p> <p>2 the doctor needs to tell me if he needs</p> <p>3 to read it first. Please don't instruct</p> <p>4 him to read it.</p> <p>5 MR. TISI: I'm objecting. I'm</p> <p>6 going to instruct him. If you're going</p> <p>7 to ask him about a section of the report,</p> <p>8 he needs to take a look at it.</p> <p>9 MR. HEGARTY: Understood,</p> <p>10 but -- and I'm fine with that.</p> <p>11 MR. TISI: Thank you.</p> <p>12 MR. HEGARTY: But if he needs</p> <p>13 to read it, he needs to tell me so we can</p> <p>14 go off the record so I'm not taking up</p> <p>15 time with him reading.</p> <p>16 MR. TISI: Well, I'm not going</p> <p>17 to go off the record. If you're going to</p> <p>18 ask him about a section of the report,</p> <p>19 he's going to read the section of the</p> <p>20 report.</p> <p>21 MR. HEGARTY: Fine.</p> <p>22 MR. TISI: If you ask him</p> <p>23 about a sentence, that's fine, but go</p> <p>24 ahead.</p>	<p style="text-align: right;">Page 112</p> <p>1 Q. Where in your report do you report</p> <p>2 exposure misclassification?</p> <p>3 A. In the review of the cohort studies.</p> <p>4 Q. Nowhere in your report do you do an</p> <p>5 analysis of confounding, correct?</p> <p>6 A. That's not true.</p> <p>7 Q. Show me in your report where you do</p> <p>8 an analysis of confounding.</p> <p>9 A. By we discuss the potential for</p> <p>10 confounding. I'm not sure what you mean by "an</p> <p>11 analysis of confounding."</p> <p>12 Q. Well, where do you discuss the</p> <p>13 potential for confounding in your report?</p> <p>14 A. My report?</p> <p>15 (Reviews document.)</p> <p>16 In the overall approach and</p> <p>17 methodological review.</p> <p>18 Q. On what page?</p> <p>19 A. On page 4. The paragraph that</p> <p>20 begins:</p> <p>21 "If no checklist for causal</p> <p>22 inference exists, then how does causal inference</p> <p>23 proceed?"</p> <p>24 And then the sentence was:</p>
<p style="text-align: right;">Page 111</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Are you there --</p> <p>3 A. Yes.</p> <p>4 Q. -- with me?</p> <p>5 A. Please ask your question.</p> <p>6 Q. Dr. Rothman writes in that section</p> <p>7 as it relates to dose response:</p> <p>8 "With rare exception, every causal</p> <p>9 relation in epidemiologic research shows a</p> <p>10 progressive relation between various measures of</p> <p>11 increasing exposure."</p> <p>12 A. Uh-huh.</p> <p>13 Q. That is a true statement, correct?</p> <p>14 MR. TISI: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. His methodology then lists five</p> <p>18 factors: exposure misclassification, recall bias,</p> <p>19 confounding, dose-response trends, and biologic</p> <p>20 mechanism, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Nowhere in your report do you</p> <p>23 analyze exposure misclassification, correct?</p> <p>24 A. Not correct.</p>	<p style="text-align: right;">Page 113</p> <p>1 "Or, was the association</p> <p>2 attributable to some other factor that causes the</p> <p>3 disease and is associated with the exposure under</p> <p>4 study?"</p> <p>5 That is the definition of</p> <p>6 confounding.</p> <p>7 Q. Do you do analysis of potential</p> <p>8 confounding factors with regard to talc and</p> <p>9 ovarian cancer in your report?</p> <p>10 A. In the evaluation of the articles,</p> <p>11 we looked to see whether confounders were taken</p> <p>12 into consideration in the assessments.</p> <p>13 Q. Nowhere in your report do you</p> <p>14 discuss the potential confounding factor of BMI,</p> <p>15 correct?</p> <p>16 A. Not -- not that I'm aware of. But,</p> <p>17 remember, a confounder has to have preceded the</p> <p>18 use of a particular exposure.</p> <p>19 Q. Nowhere in your report do you</p> <p>20 discuss the potential confounder of hormone</p> <p>21 replacement therapy, correct?</p> <p>22 A. Again, it's not considered a</p> <p>23 confounder if it doesn't -- if it's not antecedent</p> <p>24 to the risk -- to the use of the exposure.</p>

<p style="text-align: right;">Page 114</p> <p>1 Q. My question is different, though.</p> <p>2 Nowhere in your report do you</p> <p>3 discuss hormone replacement therapy as a potential</p> <p>4 confounder for the talcum powder and ovarian</p> <p>5 cancer studies, correct?</p> <p>6 A. That's correct, because it's</p> <p>7 unlikely to be a confounder.</p> <p>8 Q. Nowhere in your report do you</p> <p>9 discuss smoking as a potential confounder,</p> <p>10 correct?</p> <p>11 A. I don't believe that smoking is a</p> <p>12 strong risk factor for ovarian cancer.</p> <p>13 Q. My question is different, Doctor.</p> <p>14 My question is: Do you anywhere in</p> <p>15 your report discuss smoking --</p> <p>16 A. No.</p> <p>17 Q. -- as a potential confounder?</p> <p>18 A. No.</p> <p>19 Q. Do you discuss anywhere in your</p> <p>20 report any of the potential confounders that are</p> <p>21 listed in the studies that you reviewed looking at</p> <p>22 talcum powder use and ovarian cancer?</p> <p>23 A. I don't believe I discussed it in</p> <p>24 the report because the studies that were done and</p>	<p style="text-align: right;">Page 116</p> <p>1 So I do state that in the</p> <p>2 conclusions.</p> <p>3 Q. Please look back over to Exhibit</p> <p>4 Number 9, Dr. Rothman's 2000 document.</p> <p>5 A. Yes.</p> <p>6 Q. Report.</p> <p>7 A. Yes.</p> <p>8 Q. Over on page 6.</p> <p>9 A. Yes.</p> <p>10 Q. He does an analysis of dose response</p> <p>11 and actually has two figures there where he's</p> <p>12 analyzing the trend from the data, correct?</p> <p>13 A. It appears that is what he is doing,</p> <p>14 yes. I don't know what data he is using to derive</p> <p>15 that.</p> <p>16 Q. You did not do an analysis like</p> <p>17 it --</p> <p>18 A. No, I did not.</p> <p>19 Q. -- in your report --</p> <p>20 A. I did not.</p> <p>21 Q. -- like what is shown on page 6?</p> <p>22 A. No.</p> <p>23 MR. TISI: One at a time. One</p> <p>24 at a time. Sorry.</p>
<p style="text-align: right;">Page 115</p> <p>1 also combined together in meta-analyses had done</p> <p>2 their best job at trying to control for known risk</p> <p>3 factors for ovarian cancer.</p> <p>4 Q. Nowhere in your report do you</p> <p>5 analyze dose-response trends, correct?</p> <p>6 A. I believe that's not true.</p> <p>7 I believe at the end of my report --</p> <p>8 (Reviews document).</p> <p>9 Q. Let me ask a different way. Let me</p> <p>10 withdraw that question.</p> <p>11 A. Okay.</p> <p>12 Q. Nowhere in your report do you do an</p> <p>13 analysis of the various dose-response findings</p> <p>14 from the studies and report on what the trends are</p> <p>15 as to those studies, correct?</p> <p>16 A. I believe I could state in</p> <p>17 "Considering the preponderance of the evidence,</p> <p>18 including after controlling for known risk and</p> <p>19 protective factors for ovarian cancer, evidence of</p> <p>20 a trend of increasing risk of ovarian cancer with</p> <p>21 increasing talc applications" -- and that was</p> <p>22 evident from the 1999 publication and the 2012</p> <p>23 publication that I had done -- "especially when</p> <p>24 the vaginal tract is open to the ovaries."</p>	<p style="text-align: right;">Page 117</p> <p>1 THE WITNESS: No, and</p> <p>2 Dr. Rothman did not recommend that we do</p> <p>3 that.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Did you actually have a discussion</p> <p>6 with him about it?</p> <p>7 A. I don't recall.</p> <p>8 Q. With regard to dose response, you</p> <p>9 only cite a single study that found a</p> <p>10 dose-response trend.</p> <p>11 That's Cramer on page 8, correct?</p> <p>12 MR. TISI: Objection.</p> <p>13 Misstates.</p> <p>14 THE WITNESS: In my report?</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. In your report, Doctor.</p> <p>17 MR. TISI: Misstates the</p> <p>18 evidence and his report.</p> <p>19 THE WITNESS: Where? Where</p> <p>20 is that located?</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. In the middle paragraph of page 8</p> <p>23 above the "Cohort Studies."</p> <p>24 A. That's right. Most recent study,</p>

<p style="text-align: right;">Page 118</p> <p>1 yes.</p> <p>2 Q. You don't cite any other study in</p> <p>3 your report that discusses a dose-response trend,</p> <p>4 correct?</p> <p>5 MR. TISI: Objection.</p> <p>6 Misstates his report.</p> <p>7 THE WITNESS: Again, I</p> <p>8 selected Cramer's study as a -- as the</p> <p>9 most recent relevant article that shows a</p> <p>10 dose response.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Going back to my question.</p> <p>13 You don't discuss anywhere else in</p> <p>14 your report any other study that reported on a</p> <p>15 dose-response -- that reported a dose-response</p> <p>16 trend, correct?</p> <p>17 A. It's not specifically stated here in</p> <p>18 the report.</p> <p>19 MR. TISI: And, again,</p> <p>20 objection. There are other discussions</p> <p>21 in the report.</p> <p>22 MR. HEGARTY: Chris, come on.</p> <p>23 Let's limit your objections to --</p> <p>24 MR. TISI: Okay. I'm happy to</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. Other than -- fair point. Let's add</p> <p>2 Schildkraut.</p> <p>3 Other than Cramer and Schildkraut,</p> <p>4 you don't report an increasing trend with</p> <p>5 increasing frequency, duration, or cumulative</p> <p>6 exposure from any other study, correct?</p> <p>7 MR. TISI: Objection.</p> <p>8 Misstates his report.</p> <p>9 THE WITNESS: Okay. So, as</p> <p>10 you know, the Cramer study was the New</p> <p>11 England case-control study that was</p> <p>12 continued to build cases and controls,</p> <p>13 and so the 1992 report that we published</p> <p>14 was from that same data set with much</p> <p>15 fewer cases and controls showing a dose</p> <p>16 response.</p> <p>17 As you add more cases and</p> <p>18 controls to that particular -- that</p> <p>19 particular case and control series, you</p> <p>20 continue to see a dose response. And as</p> <p>21 you even continue to add more in the</p> <p>22 2016, it continues to show that kind of</p> <p>23 trend.</p> <p>24 So, no, I did not -- I did not</p>
<p style="text-align: right;">Page 119</p> <p>1 do that.</p> <p>2 MR. HEGARTY: -- form, and you</p> <p>3 know that that was an improper objection,</p> <p>4 and you were coaching the witness.</p> <p>5 MR. TISI: You know -- you</p> <p>6 know that you're misstating his report.</p> <p>7 MR. HEGARTY: Then it's up for</p> <p>8 the doctor to tell me I'm misstating his</p> <p>9 report.</p> <p>10 MR. TISI: No, it's up to you</p> <p>11 to ask fair questions.</p> <p>12 MR. HEGARTY: You know how</p> <p>13 that works.</p> <p>14 MR. TISI: It's up to you to</p> <p>15 ask fair questions.</p> <p>16 MR. HEGARTY: It is a fair</p> <p>17 question.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Doctor, you do actually --</p> <p>20 A. Actually -- actually, if I may, I</p> <p>21 believe also I cite Schildkraut's study --</p> <p>22 Q. Do you report on what Schildkraut --</p> <p>23 A. -- and the trend of increasing risk</p> <p>24 with increasing years and frequency of exposure</p>	<p style="text-align: right;">Page 121</p> <p>1 specifically talk about the 1992 and the</p> <p>2 1999 papers because the 2016 paper was</p> <p>3 the most recent one.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. You are not an author on Cramer's</p> <p>6 2016 paper?</p> <p>7 A. I am not, but it is from that data</p> <p>8 set.</p> <p>9 Q. You're not an author on the</p> <p>10 Schildkraut paper?</p> <p>11 A. I am not.</p> <p>12 Q. Going back to my question.</p> <p>13 The only two studies you report on</p> <p>14 as showing an increasing trend with increasing</p> <p>15 dose in your report are the Cramer and Schildkraut</p> <p>16 study, correct?</p> <p>17 MR. TISI: Objection.</p> <p>18 Misstates his report.</p> <p>19 THE WITNESS: Yeah, those --</p> <p>20 those are what was stated in the report</p> <p>21 as what I thought ample evidence to</p> <p>22 suggest that dose response is present.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. You actually cite to two studies</p>

<p style="text-align: right;">Page 122</p> <p>1 that reported no dose response, the Davis study on</p> <p>2 page 14 and the Taher study on pages 13 and 14,</p> <p>3 correct?</p> <p>4 A. The Davis study on page 13.</p> <p>5 Q. 14.</p> <p>6 A. Oh, 14. I'm sorry.</p> <p>7 Yes.</p> <p>8 Q. And then the Taher study you also</p> <p>9 report did not find an increasing trend or dose</p> <p>10 response, correct?</p> <p>11 A. However, in the Davis article, they</p> <p>12 did not lump together frequency and duration of</p> <p>13 use to get a cumulative exposure measure. So it</p> <p>14 was they did not. For whatever reason, they chose</p> <p>15 not to do that.</p> <p>16 And with the Taher study, it was --</p> <p>17 again, it was not what I would consider to be an</p> <p>18 appropriate -- a complete ascertainment of</p> <p>19 exposure.</p> <p>20 Q. You mentioned your '92 and '99</p> <p>21 study.</p> <p>22 Your -- actually your '99 study, as</p> <p>23 we looked at a short time ago, found no dose</p> <p>24 response, correct?</p>	<p style="text-align: right;">Page 124</p> <p>1 MR. HEGARTY: You can show it</p> <p>2 him when you do your questioning, Chris.</p> <p>3 You know how that works.</p> <p>4 MR. TISI: No. You know how</p> <p>5 it works. You can't ask him about a</p> <p>6 study and not show him the study.</p> <p>7 MR. HEGARTY: I can withdraw</p> <p>8 the question. That's absolutely</p> <p>9 permitted.</p> <p>10 MR. TISI: Well...</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Look over on page 355 of your</p> <p>13 article.</p> <p>14 A. Uh-huh. Hold on a second. Let</p> <p>15 me -- let me just get the article.</p> <p>16 Q. It's one of the exhibits.</p> <p>17 A. Yeah.</p> <p>18 MR. TISI: He's going to</p> <p>19 his -- his ones.</p> <p>20 THE WITNESS: Okay.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. 355. Lower left-hand corner at the</p> <p>23 bottom. Tell me when you're there.</p> <p>24 A. Yep. There.</p>
<p style="text-align: right;">Page 123</p> <p>1 MR. TISI: Objection.</p> <p>2 THE WITNESS: No, that's not</p> <p>3 true. The 1999 article with Cramer?</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Well, let me go back over what you</p> <p>6 said.</p> <p>7 A. Well, let me go look at the data.</p> <p>8 Let me pull up the article.</p> <p>9 Q. I got to ask my question.</p> <p>10 MR. TISI: Well, no. You said</p> <p>11 his article does not show a dose</p> <p>12 response. He says he wants to look at</p> <p>13 his table.</p> <p>14 MR. HEGARTY: Withdraw my --</p> <p>15 withdraw my question. Let me ask another</p> <p>16 question.</p> <p>17 MR. TISI: You can't do that.</p> <p>18 No, you can't do that.</p> <p>19 MR. HEGARTY: Yes, I can.</p> <p>20 MR. TISI: You can't do that.</p> <p>21 MR. HEGARTY: Let me ask a</p> <p>22 different question.</p> <p>23 MR. TISI: No. I want to show</p> <p>24 him the study.</p>	<p style="text-align: right;">Page 125</p> <p>1 Q. No. This part. This page.</p> <p>2 (Indicates).</p> <p>3 A. 355?</p> <p>4 Q. 355.</p> <p>5 A. Oh, I'm sorry. Yep. I'm here.</p> <p>6 Q. You wrote:</p> <p>7 "Most talc and ovarian cancer</p> <p>8 studies" --</p> <p>9 A. I'm sorry. On which? On which?</p> <p>10 Q. Lower left-hand corner.</p> <p>11 A. Okay. Got it. Yep.</p> <p>12 Q. "Most talc and ovarian cancer</p> <p>13 studies that have addressed dose response,</p> <p>14 including this one, have failed to demonstrate</p> <p>15 consistent dose response relationships with</p> <p>16 measures of the intensity of the exposure,</p> <p>17 especially when the trend is examined among users</p> <p>18 only."</p> <p>19 And you agreed with me that was a</p> <p>20 true statement back then, correct?</p> <p>21 A. Yeah, and that is a true statement.</p> <p>22 If you look at the table by which this comes and</p> <p>23 that is -- that is if you just look at -- if you</p> <p>24 just look at total applications, then you don't</p>

<p style="text-align: right;">Page 126</p> <p>1 see that dose response.</p> <p>2 But when you start to take into</p> <p>3 account the time periods when women were exposed,</p> <p>4 excluding times when subsequent to a tubal</p> <p>5 ligation or a hysterectomy, and then in addition,</p> <p>6 excluding times when there was not ovulation, you</p> <p>7 see a significant dose response going forward.</p> <p>8 Well, you see a dose response. I don't like the</p> <p>9 word "significant," but you can see that it goes</p> <p>10 from 1.0 to 1.8.</p> <p>11 So there is a dose response when you</p> <p>12 take into account a refinement of the -- an</p> <p>13 appropriate refinement of the exposure.</p> <p>14 Q. Please turn back over to Exhibit</p> <p>15 Number 9, Dr. Rothman's November 28, 2000 report.</p> <p>16 A. Yep. Yep. I have it.</p> <p>17 Q. Please turn over to page 4.</p> <p>18 A. Uh-huh.</p> <p>19 Q. In the second full paragraph on the</p> <p>20 top, about the middle of that paragraph,</p> <p>21 Dr. Rothman writes --</p> <p>22 MR. TISI: Give him a chance</p> <p>23 to get there.</p> <p>24 THE WITNESS: No, no. I'm</p>	<p style="text-align: right;">Page 128</p> <p>1 Q. Dr. Rothman writes in the first</p> <p>2 sentence:</p> <p>3 "Cohort studies do not suffer from</p> <p>4 recall bias, but recall bias is an issue for</p> <p>5 case-control studies that obtain exposure</p> <p>6 information from subject interviews."</p> <p>7 Do you agree with that statement?</p> <p>8 A. No, and neither does he because we</p> <p>9 specifically talked about the fact that cohort</p> <p>10 studies can indeed have recall bias in our report.</p> <p>11 Q. Did he agree with that statement</p> <p>12 when he wrote it back in 2000?</p> <p>13 A. I have no idea what -- what -- I</p> <p>14 think -- I have no idea what he -- I only know</p> <p>15 what he agreed to with respect to our report.</p> <p>16 And I think in his 2000 report, he</p> <p>17 was making a general conclusion about cohort</p> <p>18 studies being designed specifically to look at the</p> <p>19 exposure and unexposed, and actually recruiting</p> <p>20 participants as -- as being unexposed or not</p> <p>21 exposed and then following them forward in time.</p> <p>22 So, ideally, you're right. He's</p> <p>23 right. They would not suffer from recall bias if</p> <p>24 you are able to identify them prior to the outcome</p>
<p style="text-align: right;">Page 127</p> <p>1 fine.</p> <p>2 MR. TISI: No, I need to get</p> <p>3 you. We all need to get there.</p> <p>4 THE WITNESS: Okay.</p> <p>5 MR. TISI: He's</p> <p>6 freight-training you here on this. So</p> <p>7 let's get the documents out so you can</p> <p>8 compare what is said.</p> <p>9 THE WITNESS: Okay.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Dr. Rothman writes:</p> <p>12 "Ideally one would wish to have a</p> <p>13 measure of talc dose within the upper reproductive</p> <p>14 tract."</p> <p>15 Do you see where I'm reading?</p> <p>16 A. No, I don't. I'm sorry.</p> <p>17 Q. (Indicates).</p> <p>18 A. Oh, yeah. Got it. Okay.</p> <p>19 Q. Do you agree with that statement?</p> <p>20 A. Well, it's ideally. I don't think</p> <p>21 it's feasible or can possibly be done.</p> <p>22 Q. Please look at the next section on</p> <p>23 "Recall Bias."</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 129</p> <p>1 of interest and to be able to capture all of the</p> <p>2 exposure that occurred over a period of time.</p> <p>3 Q. Please look at the third line of</p> <p>4 that same paragraph. Dr. Rothman writes:</p> <p>5 "Recall bias can readily introduce</p> <p>6 enough bias to produce the modestly-sized overall</p> <p>7 effect (relative risk equals 1.3) that emerges</p> <p>8 from these studies."</p> <p>9 Do you agree with that statement?</p> <p>10 A. I think it's not a yes or no. I</p> <p>11 think in some situations if there is the -- if the</p> <p>12 recall bias is applicable to the exposure being</p> <p>13 assessed, and I believe there are many studies</p> <p>14 that and many comments even during the conference</p> <p>15 in 2000 -- I mean, in 1994 where Dr. Hartge</p> <p>16 specifically said those who were exposed to an</p> <p>17 event in their lifetime that was daily over</p> <p>18 decades are unlikely to have an issue related to</p> <p>19 recall bias.</p> <p>20 Q. Please turn over to page 5 of that</p> <p>21 document.</p> <p>22 A. Yes.</p> <p>23 Q. The section on "Confounding."</p> <p>24 A. Yes.</p>



<p style="text-align: right;">Page 130</p> <p>1 Q. Tell me when you're there.</p> <p>2 A. Uh-huh. I'm there.</p> <p>3 Q. Look at the very end of that</p> <p>4 section. Dr. Rothman writes:</p> <p>5 "Of course, it remains possible that</p> <p>6 yet unidentified risk factors for ovarian cancer</p> <p>7 could be important confounders, and several such</p> <p>8 factors in the aggregate could give rise to an</p> <p>9 overall association as weak as the one between</p> <p>10 talc and ovarian cancer."</p> <p>11 Do you agree with that statement?</p> <p>12 A. I think it's conceivable but not</p> <p>13 likely in this situation because any unmeasured</p> <p>14 confounder would have to have preceded the use of</p> <p>15 talc, and women have been -- the women who are</p> <p>16 greatest risk, in my view, with respect to talc</p> <p>17 have been using it for decades, even as early as</p> <p>18 their -- during -- during childhood.</p> <p>19 So to think of an unmeasured</p> <p>20 confounder that would have preceded that are -- I</p> <p>21 don't know what it could possibly be.</p> <p>22 And when people talk about obesity</p> <p>23 or hormone replacement therapy, or any of the</p> <p>24 other things, they would serve -- and if you were</p>	<p style="text-align: right;">Page 132</p> <p>1 meta-analyses -- meta-regression analysis, is not</p> <p>2 consistent with a causal interpretation for talc</p> <p>3 exposure. Instead it suggests that some as yet</p> <p>4 unidentified bias accounts for overall modest --</p> <p>5 the overall modest relation between talc exposure</p> <p>6 and ovarian cancer risk."</p> <p>7 First of all, did I read that</p> <p>8 correctly?</p> <p>9 A. You did.</p> <p>10 Q. Do you agree with those statements</p> <p>11 based on the data that Dr. Rothman reports in this</p> <p>12 part of this report?</p> <p>13 MR. TISI: Again -- again, you</p> <p>14 know, in fairness to the witness, you</p> <p>15 have picked out sentences and skipped</p> <p>16 sentences. If you're going to ask him</p> <p>17 about -- about things, let him read --</p> <p>18 let him read the paragraph and he can</p> <p>19 answer your question.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. You can answer.</p> <p>22 MR. TISI: No. He can answer</p> <p>23 when he's had -- when he feels</p> <p>24 comfortable reading it.</p>
<p style="text-align: right;">Page 131</p> <p>1 to adjust for them, they would serve as mediators</p> <p>2 and would attenuate the relative risk.</p> <p>3 Q. Please turn to the next section on</p> <p>4 "Dose-response trends."</p> <p>5 A. Yes.</p> <p>6 MR. TISI: When you get to a</p> <p>7 stopping point, we've been going for a</p> <p>8 while.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Dr. Rothman writes in the first</p> <p>11 sentence:</p> <p>12 "A nearly constant feature of causal</p> <p>13 relations in epidemiology and in the pathogenesis</p> <p>14 cancer in particular is a monotonically increasing</p> <p>15 relation between measures of exposure and disease</p> <p>16 risk."</p> <p>17 Do you agree with that statement?</p> <p>18 A. I would say in most situations</p> <p>19 that's what we are looking for.</p> <p>20 Q. Please turn to the next page,</p> <p>21 page 6.</p> <p>22 At the very top, Dr. Rothman writes:</p> <p>23 "Thus, the observed pattern, whether</p> <p>24 based on individual studies or from the combined</p>	<p style="text-align: right;">Page 133</p> <p>1 Do not feel compelled to</p> <p>2 answer questions about picked-apart</p> <p>3 sentences.</p> <p>4 THE WITNESS: Yeah. I'm ready</p> <p>5 to answer.</p> <p>6 I do not know what estimates</p> <p>7 he used for calculating these -- these</p> <p>8 curves.</p> <p>9 The other thing that I don't</p> <p>10 know is how dose was assessed in his</p> <p>11 making of these curves.</p> <p>12 So I can't really comment on</p> <p>13 that.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Please turn next over to the section</p> <p>16 of "Biologic Mechanism."</p> <p>17 MR. TISI: Wait. Since we're</p> <p>18 going to a new one, let's take a break.</p> <p>19 MR. HEGARTY: Okay. Off the</p> <p>20 record.</p> <p>21 (Recess: 11:31 a.m. -</p> <p>22 11:32 a.m.)</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. I'll finish with this document.</p>

<p style="text-align: right;">Page 134</p> <p>1 Please turn to the "Biologic Mechanism" section.</p> <p>2 A. Yes.</p> <p>3 Q. Please look towards the bottom of</p> <p>4 that paragraph.</p> <p>5 First of all, are you familiar with</p> <p>6 this section?</p> <p>7 A. Yes, I am.</p> <p>8 Q. Dr. Rothman writes towards the</p> <p>9 bottom of that section:</p> <p>10 "Without a clear biologic mechanism</p> <p>11 for talc to cause ovarian cancer, an inference</p> <p>12 that talc does cause ovarian cancer would be an</p> <p>13 example of a 'black-box' inference, meaning that</p> <p>14 the inference lacks a biologic foundation."</p> <p>15 Do you agree with that statement?</p> <p>16 A. No, I don't, and, in fact,</p> <p>17 Dr. Rothman cited our 1999 article. And if you go</p> <p>18 to read our 1999 article, there was a discussion</p> <p>19 of the biological plausibility and the fact that</p> <p>20 there was much evidence to suggest that.</p> <p>21 So I do not know why he made that</p> <p>22 conclusion.</p> <p>23 Q. You don't say anywhere in your</p> <p>24 report that there is a clear biologic mechanism</p>	<p style="text-align: right;">Page 136</p> <p>1 is unknown, plausible mechanisms may involve</p> <p>2 inflammation."</p> <p>3 Did I read that correctly?</p> <p>4 A. You did.</p> <p>5 Q. You are not citing in your report</p> <p>6 that there is -- let me start over again.</p> <p>7 You're not claiming in your report</p> <p>8 that there is a clear biologic mechanism by which</p> <p>9 talc causes ovarian cancer, correct?</p> <p>10 MS. PARFITT: Objection.</p> <p>11 MR. TISI: Objection.</p> <p>12 Misstates the standard.</p> <p>13 THE WITNESS: No, I don't</p> <p>14 believe I'm making -- I don't believe</p> <p>15 that is inferred from this statement.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. To make it clear because I'm not</p> <p>18 sure I understand your answer.</p> <p>19 You're not saying in your report</p> <p>20 anywhere that there is a clear biologic mechanism</p> <p>21 by which talc causes ovarian cancer, correct?</p> <p>22 A. That --</p> <p>23 MR. TISI: Objection.</p> <p>24 MS. PARFITT: Objection.</p>
<p style="text-align: right;">Page 135</p> <p>1 for talc to cause ovarian cancer, correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: Well, I don't</p> <p>4 believe that's true.</p> <p>5 I believe we actually at the</p> <p>6 under report -- and I'll tell you where</p> <p>7 it is. Under -- there is lack of -- on</p> <p>8 page 19, there's a section on this.</p> <p>9 There's a lack of evidence</p> <p>10 regarding the biologic plausibility of</p> <p>11 talc. That's the interpretation that</p> <p>12 others have made, and we specifically</p> <p>13 talk about a number of -- of ways in</p> <p>14 which there is a biological plausibility.</p> <p>15 It's a short section, but it</p> <p>16 certainly does not agree with what</p> <p>17 Dr. Rothman has indicated in his earlier</p> <p>18 report.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. Staying with that section in your</p> <p>21 report, at the very end of page 19 before the</p> <p>22 "Summary," you state:</p> <p>23 "Although the exact pathogenic</p> <p>24 mechanism by which talc may incur carcinogenesis</p>	<p style="text-align: right;">Page 137</p> <p>1 THE WITNESS: I am stating</p> <p>2 that there are many possible mechanisms</p> <p>3 that could be in play, but we do not know</p> <p>4 what that exact biological mechanism is.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Is it your opinion that there is a</p> <p>7 clear biologic mechanism by which talc causes</p> <p>8 ovarian cancer?</p> <p>9 MR. TISI: Objection.</p> <p>10 THE WITNESS: I believe there</p> <p>11 is.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. What is that clear biologic</p> <p>14 mechanism and where is that referenced in your</p> <p>15 report?</p> <p>16 A. I -- well, you're asking me if I</p> <p>17 believe there is a clear biological mechanism, and</p> <p>18 the biological mechanism is summarized by evidence</p> <p>19 to show transvaginal migration of top particulates</p> <p>20 by the potential for talc particulates to embed in</p> <p>21 inclusion cysts that has been shown to be able to</p> <p>22 induce inflammation.</p> <p>23 Those are all plausible biological</p> <p>24 processes that could explain the carcinogenic or</p>



<p style="text-align: right;">Page 138</p> <p>1 underlie the carcinogenic process.</p> <p>2 Q. Are you equating plausibility of</p> <p>3 these mechanisms with clear biologic mechanisms?</p> <p>4 MS. PARFITT: Objection.</p> <p>5 THE WITNESS: No. My -- my</p> <p>6 job as an epidemiologist is to be able to</p> <p>7 show biological plausibility, and I</p> <p>8 believe that has been effectively shown.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Well, have you shown in your report</p> <p>11 a clear biologic mechanism for talc to cause</p> <p>12 ovarian cancer?</p> <p>13 MR. TISI: Objection. This is</p> <p>14 now about the fifth time you've asked the</p> <p>15 question.</p> <p>16 THE WITNESS: Yeah.</p> <p>17 MR. TISI: He's talked about</p> <p>18 plausibility.</p> <p>19 Go ahead.</p> <p>20 THE WITNESS: Well, I've -- I</p> <p>21 don't believe we -- for even cigarette</p> <p>22 smoking and lung cancer that we can't</p> <p>23 specifically say what that clear</p> <p>24 pathological mechanism might be, or what</p>	<p style="text-align: right;">Page 140</p> <p>1 "Causation is the most reasonable</p> <p>2 explanation for the association between perineal</p> <p>3 exposure to talc and ovarian cancer."</p> <p>4 As to that opinion, does it apply to</p> <p>5 all subtypes of ovarian cancer?</p> <p>6 A. We evaluated it based on the</p> <p>7 totality of epithelial ovarian cancer.</p> <p>8 Q. Well, does it -- does that statement</p> <p>9 apply to mucinous ovarian cancer in talcum powder</p> <p>10 exposure?</p> <p>11 A. It was not an analysis specific to</p> <p>12 histologic subtypes. It was based on all</p> <p>13 epithelial ovarian tumors.</p> <p>14 Q. Understood.</p> <p>15 But sitting here today, is it your</p> <p>16 opinion that talcum powder use in the genital area</p> <p>17 causes mucinous adenocarcinoma?</p> <p>18 A. I can't respond to that because</p> <p>19 there are -- the studies that are in the</p> <p>20 literature were not designed to specifically</p> <p>21 target, for example, a case-control study of</p> <p>22 mucinous ovarian cancer.</p> <p>23 They did a case-control study of</p> <p>24 epithelial ovarian cancer, and then based on</p>
<p style="text-align: right;">Page 139</p> <p>1 the chemical component in the cigarettes</p> <p>2 are that are specifically inducing the</p> <p>3 cancer.</p> <p>4 We know, but I believe it's</p> <p>5 indisputable that people believe that</p> <p>6 cigarettes cause -- cause lung cancer.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Can you then translate that to talc</p> <p>9 and ovarian cancer?</p> <p>10 A. Yes. I don't believe we know what</p> <p>11 the actual clear pathogenic mechanism is, but</p> <p>12 there are multiple possibilities that would make</p> <p>13 it a biologically plausible explanation for the</p> <p>14 association that we see.</p> <p>15 MR. HEGARTY: We can take that</p> <p>16 break. Go off the record.</p> <p>17 MR. TISI: Thank you so much.</p> <p>18 (Recess: 11:37 a.m. -</p> <p>19 11:48 a.m.)</p> <p>20 MR. HEGARTY: We're back on</p> <p>21 the record.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Doctor, looking at page 6 of your</p> <p>24 report, it also has your conclusion that:</p>	<p style="text-align: right;">Page 141</p> <p>1 however many cases they had of the various</p> <p>2 subtypes, they looked at those, but those studies</p> <p>3 were not designed specifically to look at the</p> <p>4 specific risk factors for that particular</p> <p>5 histologic subtype.</p> <p>6 And I think the approach that's been</p> <p>7 used throughout the literature is to keep</p> <p>8 epithelial ovarian tumors lumped together.</p> <p>9 Q. Understanding that, but is it your</p> <p>10 opinion that talcum powder use in the genital area</p> <p>11 causes clear cell adenocarcinoma?</p> <p>12 MS. PARFITT: Objection.</p> <p>13 THE WITNESS: I believe I</p> <p>14 answered that.</p> <p>15 I believe my statement refers</p> <p>16 to all -- to epithelial ovarian cancer as</p> <p>17 a whole, knowing that 90 percent of</p> <p>18 epithelial ovarian cancers are serous.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. Is it your opinion that talcum</p> <p>21 powder use in the genital area causes clear cell</p> <p>22 adenocarcinoma?</p> <p>23 A. This was -- again, my same response</p> <p>24 is 90 percent of epithelial ovarian tumors are</p>

<p style="text-align: right;">Page 142</p> <p>1 serous, and all the other histologic subtypes are  2 much smaller in terms of numbers that are found in  3 the studies and, therefore, I cannot make that  4 kind of conclusion.  5 Q. Is it your opinion that genital talc  6 use in the -- start over again.  7 Is it your opinion that talc use in  8 the genital area causes serous adenocarcinoma?  9 A. Given that serous cancer makes up  10 about 90 percent of the incidents, I would say  11 yes.  12 Q. In your report in the Executive  13 Summary, second paragraph about four lines down,  14 when you're referring to talc and ovarian cancer  15 you say:  16 "An association that is stronger and  17 more consistent for the subtype" --  18 A. I'm sorry. I didn't mean to  19 interrupt. Show me where exactly in the Executive  20 Summary.  21 MR. TISI: Do you mind me  22 showing him?  23 THE WITNESS: "An association  24 that is stronger."</p>	<p style="text-align: right;">Page 144</p> <p>1 and serous ovarian cancer?  2 A. No, because the studies, as I  3 indicated before, were not designed to be able to  4 look at those subtypes. And the reason we could  5 look at it with serous is because they make up the  6 majority of the cases.  7 Q. Without doing that analysis, how can  8 you say in your report that the association is  9 stronger and more consistent for the subtype of  10 serous ovarian cancer?  11 In other words, wouldn't you have to  12 do an analysis between serous and the other  13 subtypes to make that statement?  14 A. Well, others have looked at  15 specifically the serous tumors and found the  16 association to be more strongly when it's  17 restricted to that particular ones, and it doesn't  18 necessarily suggest that the others -- that there  19 isn't an association with the others.  20 I believe it suggests that that  21 particular histologic subtype seems to show an  22 association consistently.  23 Q. But to be clear, you did not do a  24 separate analysis of comparing the risk ratios or</p>
<p style="text-align: right;">Page 143</p> <p>1 I have it. Thanks. Go ahead.  2 BY MR. HEGARTY:  3 Q. Let me go back to my question.  4 In your report, you state in the  5 second paragraph as it relates to frequent talc  6 use and ovarian cancer:  7 "An association that is stronger and  8 more consistent for the subtype of serous ovarian  9 cancer."  10 First of all, did I read that  11 correctly?  12 A. Well, you only read part of the  13 sentence.  14 "The principal finding from the  15 literature is a consistent association between  16 frequent talc use and ovarian cancer."  17 That's the first part, and then it  18 says:  19 "An association that is stronger and  20 more consistent for the subtype of serous ovarian  21 cancer."  22 Q. Did you do an analysis as it relates  23 to the strength and consistency of the other  24 subtypes, clear cell, endometrioid, and mucinous,</p>	<p style="text-align: right;">Page 145</p> <p>1 odds ratios between clear cell, endometrioid, and  2 mucinous to serous?  3 A. Not in my evaluation. Not in this  4 particular report. Though, in my earlier  5 publications, I have stratified it out.  6 Q. Does your overall opinion as it  7 relates to epithelial ovarian cancer and talc use  8 apply to borderline tumors?  9 A. I think my -- as I recall, my study  10 in 1999 may have been the few studies to look at  11 borderline ovarian tumors and given that -- yeah.  12 So I don't believe that there is --  13 besides my article, there haven't been a lot of  14 any other studies I'm aware of that are  15 specifically focusing on borderline ovarian  16 tumors.  17 Q. Understood, but going back to my  18 question.  19 Does your opinion as it relates to  20 epithelial ovarian cancer and talc use apply to  21 borderline tumors?  22 A. Yes, I believe it does.  23 Q. And did you do any particular  24 analysis in your report as it relates to</p>

<p style="text-align: right;">Page 146</p> <p>1 borderline tumors and talcum powder exposure?</p> <p>2 A. I don't believe we specifically</p> <p>3 stated that in the report.</p> <p>4 Q. Is it your opinion that healthy</p> <p>5 women who have used talc in the genital area</p> <p>6 should have their tubes and ovaries removed?</p> <p>7 A. I don't believe I --</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: That's not --</p> <p>10 that's a clinical decision. I'm not a</p> <p>11 clinician.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Is it your opinion that talc used in</p> <p>14 the genital area causes vaginal cancer?</p> <p>15 A. I didn't review that literature.</p> <p>16 Q. Same question as to cervical cancer.</p> <p>17 A. I did not review that literature.</p> <p>18 Q. So you don't have an opinion?</p> <p>19 A. I don't have an opinion on that.</p> <p>20 Q. Do you have an opinion one way or</p> <p>21 the other as to talcum powder causes endometrial</p> <p>22 cancer?</p> <p>23 A. I don't have an opinion on that.</p> <p>24 Q. Do you have an opinion as to whether</p>	<p style="text-align: right;">Page 148</p> <p>1 cancer that the approach, as an epidemiologist and</p> <p>2 those who are scientists in that area, are to come</p> <p>3 up with hypotheses and to test them and to see if</p> <p>4 they might help us identify other factors that we</p> <p>5 can intervene on, and that's why some of those</p> <p>6 papers that you're citing were done to be able to</p> <p>7 try to open up new avenues of potential</p> <p>8 etiological predictors. Because that's what we</p> <p>9 really need to do to create interventions for this</p> <p>10 problem.</p> <p>11 Q. Regarding your causation opinions on</p> <p>12 talc use and epithelial ovarian cancers, do you</p> <p>13 have an opinion as to the level of increased risk</p> <p>14 the talcum powder use causes?</p> <p>15 MR. TISI: Objection.</p> <p>16 Incomplete.</p> <p>17 THE WITNESS: Well, I've</p> <p>18 stated multiple times that I believe the</p> <p>19 risk -- and I believe I said this in my</p> <p>20 view article in 1994 -- that the risk</p> <p>21 falls somewhere between 1.0 and 1.8 and</p> <p>22 that it's quite likely that it falls in</p> <p>23 the middle.</p> <p>24 BY MR. HEGARTY:</p>
<p style="text-align: right;">Page 147</p> <p>1 talcum powder use causes uterine cancer?</p> <p>2 A. I didn't do a review of the uterine</p> <p>3 cancer literature.</p> <p>4 Q. You have been an author on other</p> <p>5 studies reporting positive findings on certain</p> <p>6 exposures and ovarian cancer.</p> <p>7 Is it your opinion that these --</p> <p>8 from these studies that psychotropic medications</p> <p>9 that include antidepressants cause ovarian cancer?</p> <p>10 A. I didn't review the literature on</p> <p>11 psychotropic medication and its association with</p> <p>12 ovarian cancer. I -- we found a particular</p> <p>13 association in our own research, but in order for</p> <p>14 me to have a view on that, I would need to see</p> <p>15 what others have done and whether they were able</p> <p>16 to replicate my findings or dispute my findings.</p> <p>17 Q. Would your answer be the same if I</p> <p>18 ask you about your studies on coffee and caffeine</p> <p>19 and dairy products?</p> <p>20 A. Yes, my -- my answer would be the</p> <p>21 same.</p> <p>22 And if I -- if I may?</p> <p>23 Ovarian -- there are so few</p> <p>24 modifiable factors that we know about ovarian</p>	<p style="text-align: right;">Page 149</p> <p>1 Q. Is that still your opinion today?</p> <p>2 A. Yes.</p> <p>3 Q. You --</p> <p>4 A. Overall. Overall.</p> <p>5 Q. You agree that not everyone then who</p> <p>6 has used talcum powder on the genital area will</p> <p>7 get ovarian cancer?</p> <p>8 A. Absolutely, just like I believe that</p> <p>9 everybody -- not everybody who smokes cigarettes</p> <p>10 will get lung cancer.</p> <p>11 Q. All women are at some level of risk</p> <p>12 of developing ovarian cancer in their life</p> <p>13 sometime, correct?</p> <p>14 MS. PARFITT: Objection.</p> <p>15 Form.</p> <p>16 THE WITNESS: All women who</p> <p>17 have ovaries.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Women who have been talcum powder</p> <p>20 users in the genital area can get ovarian cancer</p> <p>21 unrelated to their talcum powder use, correct?</p> <p>22 A. Yes, I believe that to be the case.</p> <p>23 Q. With regard to the phrase you used</p> <p>24 in your report "talcum powder applied to the</p>

<p style="text-align: right;">Page 150</p> <p>1 genital area of women," is it your opinion that</p> <p>2 there is causation for a woman who has had a</p> <p>3 single application of talc to the genital area?</p> <p>4 A. I think the causation that I've</p> <p>5 indicated is predicated on exposure for a long</p> <p>6 period of time over decades.</p> <p>7 Q. Hopefully, that was where I was</p> <p>8 going to start with that question.</p> <p>9 What is the necessary exposure level</p> <p>10 of talcum powder use in the genital area to get to</p> <p>11 your causation opinion?</p> <p>12 MR. TISI: Objection.</p> <p>13 Objection --</p> <p>14 THE WITNESS: I don't --</p> <p>15 MR. TISI: -- to form.</p> <p>16 THE WITNESS: I don't believe</p> <p>17 there is a known dose that needs to be</p> <p>18 present for there to be a risk, and I</p> <p>19 would expect that other factors that are</p> <p>20 present that might promote ovarian cancer</p> <p>21 might work with the exposure of talc. We</p> <p>22 just -- we just don't know.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Do you have an opinion, sitting here</p>	<p style="text-align: right;">Page 152</p> <p>1 wish.</p> <p>2 THE WITNESS: I do not have</p> <p>3 an opinion that there is a particular</p> <p>4 amount of exposure that is necessary to</p> <p>5 put a woman at greater risk of ovarian</p> <p>6 cancer, but that the risk increases with</p> <p>7 greater amount of exposure.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. You mentioned earlier that the use</p> <p>10 has to be decades.</p> <p>11 Do you remember telling me that?</p> <p>12 MR. TISI: Objection.</p> <p>13 THE WITNESS: In my -- my</p> <p>14 view, that -- that decades of use would</p> <p>15 -- are certainly those that are at the</p> <p>16 highest risk, in my opinion.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. When you say "decades of use," how</p> <p>19 many decades?</p> <p>20 A. I don't have a particular number,</p> <p>21 but -- I don't have a particular number, but</p> <p>22 decades implies regular use for a long period of</p> <p>23 time directly applied to the perineal area.</p> <p>24 Q. In fact, in your report, you do talk</p>
<p style="text-align: right;">Page 151</p> <p>1 today, as to the necessary frequency and duration</p> <p>2 of talcum powder use for it to be causal with</p> <p>3 regard to ovarian cancer?</p> <p>4 MR. TISI: Objection to form.</p> <p>5 THE WITNESS: No, I don't.</p> <p>6 It's quite possible that somebody who</p> <p>7 smokes one or two cigarettes a day can be</p> <p>8 at risk of lung cancer, just as somebody</p> <p>9 who applies talc only once a week could</p> <p>10 be at increased risk, but the greatest</p> <p>11 risk, as in cigarette smoking and lung</p> <p>12 cancer, is with the greatest amount of</p> <p>13 exposure during vulnerable periods of</p> <p>14 time.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Understanding you may not have an</p> <p>17 opinion.</p> <p>18 My question is: Do you have an</p> <p>19 opinion, sitting here today, as to whether there</p> <p>20 is a minimum level of duration and frequency that</p> <p>21 is necessary for talcum powder use to be causal?</p> <p>22 MR. TISI: Objection. He just</p> <p>23 answered that question.</p> <p>24 You may answer it again if you</p>	<p style="text-align: right;">Page 153</p> <p>1 about in relation to your opinions that the use</p> <p>2 must be frequent, correct, to be causal?</p> <p>3 A. And where do I state that, please?</p> <p>4 Q. Well, you state that -- well, I can</p> <p>5 ask in a different way.</p> <p>6 Look over to page 20.</p> <p>7 A. Yes.</p> <p>8 Q. The second full paragraph that</p> <p>9 begins:</p> <p>10 "It appears to us that the most</p> <p>11 plausible interpretation of the existing data is</p> <p>12 that women exposed to talc for a long period of</p> <p>13 time are at greater risk of developing ovarian</p> <p>14 cancer than women who were never exposed, as a</p> <p>15 result of their talc exposure."</p> <p>16 How do you define for purpose of</p> <p>17 your report a long period of time?</p> <p>18 A. You're asking me to make a</p> <p>19 dichotomous answer that 20 years is. If somebody</p> <p>20 -- it's just like -- it's just like a p-value.</p> <p>21 Just because it's more than 20 -- somebody -- if</p> <p>22 you use 20 years as a cut point, then one would</p> <p>23 infer that, okay, it's okay to use it for 19</p> <p>24 years, and that's just not the case.</p>

<p style="text-align: right;">Page 154</p> <p>1 The frequency is more of a linear</p> <p>2 kind of an assessment, in my view. There isn't a</p> <p>3 cut point by which you can then define somebody as</p> <p>4 saying, It's okay to use it for this number of</p> <p>5 years, but not that number of years. That</p> <p>6 information is just not known.</p> <p>7 Q. My question is a little bit</p> <p>8 different than that.</p> <p>9 When you wrote the phrase "A long</p> <p>10 period of time," what were you meaning by that</p> <p>11 phrase?</p> <p>12 A. The counterfactual to that the would</p> <p>13 be a short period of time. So not a short period</p> <p>14 of time but a long period of time.</p> <p>15 Q. So when you wrote the phrase "A long</p> <p>16 period of time," you did not have a particular</p> <p>17 frequency or duration in mind; is that fair?</p> <p>18 A. That -- I think that's fair, and in</p> <p>19 the publications that I've authored, we actually</p> <p>20 use applications as the exposure as opposed to 20</p> <p>21 years. Because somebody could have used talc for</p> <p>22 20 years but only applied it once a week or only</p> <p>23 on diaphragms and, therefore, using that kind of</p> <p>24 frequent -- frequency in terms of years is not --</p>	<p style="text-align: right;">Page 156</p> <p>1 THE WITNESS: Do I believe</p> <p>2 the cause of most ovarian cancers is</p> <p>3 unknown.</p> <p>4 I would say it is more likely</p> <p>5 that the cause of ovarian cancer -- that</p> <p>6 there are causes of ovarian cancers that</p> <p>7 are unknown than that are known.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. With regard to risks for ovarian</p> <p>10 cancer generally, do gene mutation such as BRCA1</p> <p>11 or BRCA2 cause ovarian cancer?</p> <p>12 A. Yes.</p> <p>13 Q. Do the Lynch syndrome genes cause</p> <p>14 ovarian cancer?</p> <p>15 A. I believe so.</p> <p>16 Q. Does endometriosis cause</p> <p>17 endometrioid ovarian cancer?</p> <p>18 A. I'm not sure of that literature.</p> <p>19 Q. Does endometriosis cause clear cell</p> <p>20 adenocarcinoma?</p> <p>21 A. I'm not -- I'm not familiar with</p> <p>22 that literature.</p> <p>23 Q. Does HRT use -- hormone replacement</p> <p>24 therapy use cause ovarian cancer?</p>
<p style="text-align: right;">Page 155</p> <p>1 is not accurate.</p> <p>2 Q. And going back to the Executive</p> <p>3 Summary section on page 6.</p> <p>4 A. Yes.</p> <p>5 Q. Going back to that phrase we were</p> <p>6 talking about with regard to serous ovarian</p> <p>7 cancer.</p> <p>8 A. Uh-huh.</p> <p>9 Q. You use a phrase "is a consistent</p> <p>10 association between frequent talc use and ovarian</p> <p>11 cancer."</p> <p>12 What were you meaning when you said</p> <p>13 "frequent" in that sentence?</p> <p>14 A. Applications.</p> <p>15 Q. Did you have a particular number in</p> <p>16 mind either by week or by month or by total?</p> <p>17 A. Well, the only number that I can</p> <p>18 look at is that which was cited in our papers, and</p> <p>19 I believe that was more than 10,000 applications</p> <p>20 is where we saw the greatest risk. I believe that</p> <p>21 to be the case.</p> <p>22 Q. Do you agree that the cause of most</p> <p>23 ovarian cancers is unknown?</p> <p>24 MR. TISI: Objection.</p>	<p style="text-align: right;">Page 157</p> <p>1 A. Again, I didn't review the extent of</p> <p>2 that literature for the purpose of this meeting.</p> <p>3 Q. Does obesity cause ovarian cancer?</p> <p>4 A. I have not reviewed that literature</p> <p>5 either.</p> <p>6 Q. Does polycystic ovarian syndrome</p> <p>7 cause ovarian cancer?</p> <p>8 A. I have not reviewed those -- those</p> <p>9 items either.</p> <p>10 Q. My questions all included the word</p> <p>11 "cause."</p> <p>12 Do you know whether any of those</p> <p>13 subject areas, any of those exposures are risk</p> <p>14 factors for ovarian cancer? Can you say that?</p> <p>15 A. Yes, I think that there is evidence.</p> <p>16 Certainly there have been studies that have shown</p> <p>17 that obesity seems to be associated with ovarian</p> <p>18 cancer in some studies.</p> <p>19 I don't remember all the other ones</p> <p>20 that you mentioned.</p> <p>21 Q. Let me go back over them then.</p> <p>22 Is endometriosis a risk factor for</p> <p>23 endometrioid ovarian adenocarcinoma?</p> <p>24 A. Yeah. I'm not familiar with that</p>



<p style="text-align: right;">Page 158</p> <p>1 literature.</p> <p>2 Q. Is hormone replacement therapy use a</p> <p>3 risk factor for ovarian cancer?</p> <p>4 A. I believe hormone replacement</p> <p>5 therapy has been shown to be associated with most</p> <p>6 of the estrogen-related cancers.</p> <p>7 Q. Is polycystic ovarian syndrome a</p> <p>8 risk factor for ovarian cancer?</p> <p>9 A. I'm not familiar with that</p> <p>10 literature.</p> <p>11 Q. Is incessant ovulation a risk factor</p> <p>12 for ovarian cancer?</p> <p>13 A. It's a hypothesis that Dr. Cramer</p> <p>14 has put forward as a potential mechanism by which</p> <p>15 ovarian cancer might occur.</p> <p>16 Q. Is douching a risk factor for</p> <p>17 ovarian cancer, in your opinion?</p> <p>18 A. I'm not familiar with the extent of</p> <p>19 that literature.</p> <p>20 Q. Is smoking a risk factor for ovarian</p> <p>21 cancer, in your opinion?</p> <p>22 A. Again, I'm not -- I'm not up to date</p> <p>23 on that literature.</p> <p>24 Q. Is Ashkenazi Jewish heritage a risk</p>	<p style="text-align: right;">Page 160</p> <p>1 factors that are present in a particular</p> <p>2 person and making a qualitative opinion</p> <p>3 as to whether it is more likely than not</p> <p>4 that the ovarian cancer could have been</p> <p>5 attributed to one factor versus another.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Do you know of any publication where</p> <p>8 that methodology has been set out?</p> <p>9 MR. TISI: Objection. He's</p> <p>10 not case-specific person.</p> <p>11 THE WITNESS: I don't believe</p> <p>12 I'm aware of that.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Do you agree that case-control</p> <p>15 studies are more subject to recall bias than</p> <p>16 cohort studies?</p> <p>17 MR. TISI: Objection.</p> <p>18 THE WITNESS: I think</p> <p>19 correctly done case-control studies and</p> <p>20 correctly done cohort studies are -- let</p> <p>21 me rephrase that answer.</p> <p>22 I think it depends on the</p> <p>23 particular exposure that's being</p> <p>24 measured. I think that both case-control</p>
<p style="text-align: right;">Page 159</p> <p>1 factor for ovarian cancer?</p> <p>2 A. I believe it is.</p> <p>3 Q. Does a family history of ovarian</p> <p>4 cancer increase the risk of ovarian cancer?</p> <p>5 A. Yes, it does.</p> <p>6 Q. Does a family history of breast</p> <p>7 cancer increase the risk of ovarian cancer?</p> <p>8 A. Yes, it does.</p> <p>9 Q. Does a woman's risk of ovarian</p> <p>10 cancer go up with age?</p> <p>11 A. Yes, as do most cancers.</p> <p>12 Q. Are you aware of any established</p> <p>13 medical -- let me start over again.</p> <p>14 Are you aware of any established</p> <p>15 reliable methodology for determining whether a</p> <p>16 specific patient's use of talc in the genital area</p> <p>17 caused her ovarian cancer?</p> <p>18 MR. TISI: Objection.</p> <p>19 THE WITNESS: I don't believe</p> <p>20 there is any documented checklist, if you</p> <p>21 may -- if I may.</p> <p>22 It's more of a qualitative</p> <p>23 assessment of looking at competing risk</p> <p>24 factors associated -- competing risk</p>	<p style="text-align: right;">Page 161</p> <p>1 studies and cohort studies can be subject</p> <p>2 -- can be subject to a certain amount of</p> <p>3 recall bias.</p> <p>4 So it really depends on what</p> <p>5 the exposure is that you're looking at</p> <p>6 and how the study was designed.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. With regard to your discussion about</p> <p>9 recall bias, did you discuss the Schildkraut</p> <p>10 paper's analysis of recall bias in its study?</p> <p>11 A. In my report?</p> <p>12 Q. In your report, Doctor.</p> <p>13 A. (Reviews document.)</p> <p>14 In my report, I do not refer to</p> <p>15 Schildkraut.</p> <p>16 MR. HEGARTY: Let me show you</p> <p>17 Schildkraut 2016 I marked as Exhibit</p> <p>18 Number 10.</p> <p>19 (Document marked for</p> <p>20 identification as Harlow Exhibit 10.)</p> <p>21 THE WITNESS: Yep.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Are you familiar with this study?</p> <p>24 A. I am.</p>



<p style="text-align: right;">Page 162</p> <p>1 Q. In fact, you do cite to it in your 2 expert report, correct? 3 A. Yes, I do. 4 Q. Please turn over to page 412 in this 5 document. 6 A. Okay. I just wanted -- I'm sorry. 7 Page 12? 8 Q. 412. 9 A. 412. 10 MR. TISI: I'm sorry. Did you 11 say 412? It's 14. 12 MR. HEGARTY: 1412. I'm 13 sorry. 1412. 14 THE WITNESS: Hmm. The 15 numbers -- the numbers in mine don't go 16 that way. 17 MR. TISI: Oh, you have a 18 different. 19 THE WITNESS: I have a 20 different copy, but that's okay. 21 MR. TISI: I'd like you to 22 look if you have it. 23 THE WITNESS: Well, let me. 24 I'll see. 412?</p>	<p style="text-align: right;">Page 164</p> <p>1 A. I believe so, yes. 2 Q. There they reported that with regard 3 to interviews pre-2014, their point estimate was 4 1.19 with a confidence interval of .87 to 1.63; 5 and their point estimate for post-2014 interviews 6 was 2.91 with a confidence interval of 1.7 to 7 4.97. 8 Correct? 9 A. Yeah. I'm just looking to see if 10 it's in the tables. 11 Q. It is over in the table over on 12 Table 4 -- Table 2 on page 1414. 13 A. Yeah. Oh, there it is. Interview 14 date created on '14. Okay. 15 Q. Are you with me? 16 A. I will be in a second. 17 MR. TISI: Take your time and 18 look at it. 19 THE WITNESS: Confidence 20 interval greater than '14, less than '14. 21 Yes, I now see that. Okay. 22 BY MR. HEGARTY: 23 Q. The authors found an effect for 24 modification by year that was statistically</p>
<p style="text-align: right;">Page 163</p> <p>1 MR. TISI: 1412. 2 THE WITNESS: 1412. Okay. 3 The "Materials and Method" section. 4 BY MR. HEGARTY: 5 Q. I'm looking at the "Statistical 6 analysis" section at the very bottom on the 7 right-hand column. 8 A. Yep. 9 Q. The authors at the end of the 10 right-hand column recognize that lawsuits were 11 filed in 2014 regarding the possible carcinogenic 12 effect of -- of talc and ovarian cancer, and then 13 they analyzed the data pre- and post-2014, 14 correct? 15 A. Let me just take a read of that. If 16 that's okay. 17 (Reviews document.) 18 Yes, I see that. 19 Q. Please turn over to the next page 20 under the "Results" section, left-hand column 21 towards the bottom. 22 A. Uh-huh. 23 Q. Do you see where I'm focusing you 24 on?</p>	<p style="text-align: right;">Page 165</p> <p>1 significant, correct? 2 A. They found a -- they found an 3 association of -- of 2.91 for any genital use in 4 those whose interview date was greater than 2014. 5 Q. I understand, but they also did a 6 statistical analysis between the 1.19 -- 7 A. Oh, right. 8 Q. -- and the 2.91 and found that -- 9 A. Yes. 10 Q. -- found the effect by modification 11 by year of interview was statistically 12 significant, correct? 13 And if you want to look, it's in the 14 "Results" section. 15 A. No, no, no. I understand. 16 Yes, they reported that. They 17 reported that. That is correct. 18 Q. That analysis indicates that recall 19 bias had an effect based on year of interview, 20 correct? 21 A. No, it doesn't. 22 Q. How does it not show that? 23 A. It doesn't because we don't know 24 whether women were recalling after 2014 because of</p>

<p style="text-align: right;">Page 166</p> <p>1 litigation, and we also don't know anything about 2 the dose that those were using in before 2014 or 3 after 2014. 4 Q. You would not conclude that that 5 analysis that I just went through is any evidence 6 at all of recall bias; is that correct? 7 MR. TISI: Objection. 8 THE WITNESS: I think it 9 could be explained by a lot of things. 10 And I'm not suggesting that recall bias 11 doesn't play a role, but I'm certainly 12 not -- I'm not considering that recall 13 bias is the explanation for it. 14 BY MR. HEGARTY: 15 Q. You also cite in your report to the 16 Davis study; is that correct? 17 A. I do. 18 MR. TISI: I'm sorry. What 19 was this marked? I apologize. 20 MR. HEGARTY: 10. 21 I'm going to mark as Exhibit 22 Number 11 the 2021 Davis study. 23 (Document marked for 24 identification as Harlow Exhibit 11.)</p>	<p style="text-align: right;">Page 168</p> <p>1 1.11 to 1.86) compared with those who did not 2 report any powder use. When the time period was 3 limited to women who were interviewed prior to 4 2014, (i.e., before ongoing lawsuits about genital 5 powder use which had extensive media coverage), 6 the results were attenuated and no longer 7 significant (odds ratios equals 1.19; 95% 8 confidence interval .87 to 1.63). In contrast, a 9 significant positive association was observed 10 among those interviewed after 2014 (odds ratio of 11 2.91; 95% confidence interval 1.70 to 4.91; 12 reference 11). These results highlight the 13 potential for recall bias in case-control studies, 14 especially those conducted after 2013." 15 Do you dispute any of the statements 16 that I just read to you? 17 A. I don't dispute any of the 18 statements, but I want -- I would like to be 19 recognized as saying that recall bias is -- in 20 this situation is based on any use and, therefore, 21 those women who perhaps were using it infrequently 22 might have been more influenced by the knowledge 23 about litigation than -- than or not. 24 I mean, I don't -- I don't believe</p>
<p style="text-align: right;">Page 167</p> <p>1 THE WITNESS: Uh-huh. Thank 2 you. 3 BY MR. HEGARTY: 4 Q. Do you have that in front of you, 5 Doctor? 6 A. I do. 7 MS. PARFITT: Mark, I don't 8 know if you have it up there. I have a 9 clarification. Do you have a public 10 access one published online for Davis? 11 MR. HEGARTY: Well, it's the 12 one that I marked as an exhibit. 13 MS. PARFITT: I can't see. 14 MR. HEGARTY: It's published 15 online first June 21, 2021. 16 MS. PARFITT: I didn't see 17 that. Thank you. 18 BY MR. HEGARTY: 19 Q. Please turn over to page 1665. 20 A. Uh-huh. 21 Q. The text begins on that page: 22 "In AACES, women who ever used 23 genital powder had a 44% higher risk of ovarian 24 cancer (odds ratio 1.44; 95% confidence interval</p>	<p style="text-align: right;">Page 169</p> <p>1 -- let me just say this. 2 The recall bias does not take into 3 account those who used it consistently for a long 4 period of time. I don't know in this analysis to 5 what extent those before 2014 versus those after 6 2014 had varying levels of exposure. 7 And so you're making -- there's an 8 assumption being made that the reason for the 9 recall bias is because of the knowledge of 10 litigation, and there's no evidence here to show 11 that that is, in fact, the truth. 12 These women were not asked whether 13 or not they knew about the litigation in these -- 14 in these studies. 15 Q. The authors in the paper we're 16 looking at, the Davis paper, did indicate that 17 that could be a possible driver of the difference 18 between the two relative risks; is that correct? 19 A. That is -- well, I don't see it 20 specifically where they stated it, but I'm not -- 21 yes to -- yes, with the restriction of cases in 22 control. 23 Q. Are you aware of any other 24 case-control or cohort study involving talc or</p>

<p style="text-align: right;">Page 170</p> <p>1 ovarian cancer that stratified results as  2 Schildkraut did by date of interview or otherwise  3 to try to assess recall bias?  4 A. Yes. There was a recent article by  5 Goodman, I believe, that looked at -- at a  6 quantitative bias analysis to see whether or not  7 recall bias could influence -- could be explaining  8 the association that was observed --  9 Q. My question was not a review  10 article.  11 A. -- in this study.  12 Q. My question was: Are you aware of  13 any case-control or cohort studies that where the  14 authors themselves tried to stratify the results  15 by interview date or otherwise to assess the  16 potential for recall bias as Schildkraut did?  17 A. Off the top of my head, I can't  18 remember if there were.  19 Q. Let's look at your review paper that  20 you did with Dr. Hartge.  21 Is that how you say her name?  22 A. Hartge.  23 Q. Hartge?  24 A. Yes.</p>	<p style="text-align: right;">Page 172</p> <p>1 "errors in the data collected, principally because  2 of errors in recollection or reporting of talc  3 exposure."  4 That's what you wrote, correct?  5 A. That's correct.  6 Q. Turning over to pages 257 and 258,  7 starting at the bottom under the section  8 "Recollection of Talc Exposures."  9 A. Yes.  10 Q. Are you with me?  11 A. Yes.  12 Q. You wrote there:  13 "If exposures to talc were recalled  14 differently by cases and controls, relative risk  15 estimates would be distorted."  16 That's a true statement, correct?  17 A. That is what I said.  18 Q. That's also true?  19 A. No, it's not necessarily because  20 there have been new studies since here that have  21 evaluated whether or not there is substantial  22 differential or differential misclassification  23 by -- in case-control studies showing that it had  24 very little effect.</p>
<p style="text-align: right;">Page 171</p> <p>1 MR. HEGARTY: I'm going to  2 mark this review paper, which is from  3 1995, as Exhibit 12.  4 (Document marked for  5 identification as Harlow Exhibit 12.)  6 THE WITNESS: Yes.  7 BY MR. HEGARTY:  8 Q. Is Exhibit 12 your review paper with  9 Dr. Hartge?  10 A. It is.  11 Q. Do you have that paper in front of  12 you?  13 A. I do.  14 Q. Please turn over to page 256.  15 A. Yep.  16 Q. In the section "Limitations and  17 Biases in Results From Epidemiological Study."  18 Do you see that section?  19 A. I do.  20 Q. In that section, you make note that  21 the current data on talc use and ovarian cancer is  22 all from case-control studies.  23 You say that "their limitations stem  24 from three primary sources." The third being</p>	<p style="text-align: right;">Page 173</p> <p>1 One was done by -- I believe I cited  2 them in my report. One was done by Sandra  3 Greenland, and another was done by another person,  4 and I believe it was around fetal -- fetal death  5 syndrome.  6 Q. But with regard to the statement  7 we're looking at --  8 A. Yes.  9 Q. -- in a general sense, "if exposures  10 to talc were recalled differently by cases and  11 controls, relative risk estimates would be  12 distorted."  13 That is a correct statement?  14 A. I guess it would be. I guess it  15 would be a correct statement.  16 I guess the extent to which it's  17 distorted -- and, again, this was a correct  18 statement written in 1994. There has been a lot  19 of work that has been done to refine the extent to  20 which differential misclassification impacts risk  21 estimates.  22 Q. But that statement just standing by  23 itself is a correct statement?  24 A. It's what was written in this</p>

<p style="text-align: right;">Page 174</p> <p>1 article at -- in 1994.</p> <p>2 Q. It was correct at that time?</p> <p>3 A. At that time, it was what we knew.</p> <p>4 Q. Please turn to the next page. You</p> <p>5 wrote:</p> <p>6 "Cases could overreport talc use if</p> <p>7 they were anxious to assign a cause to their</p> <p>8 cancer or underreport it if they were anxious to</p> <p>9 avoid providing this information."</p> <p>10 That is also a true statement,</p> <p>11 correct?</p> <p>12 A. It is a statement that is written.</p> <p>13 Correct.</p> <p>14 Q. Is it a true statement?</p> <p>15 A. It's possible because it says</p> <p>16 "could."</p> <p>17 Q. You certainly believed that at the</p> <p>18 time you wrote it?</p> <p>19 A. It's not that I believe it. I am</p> <p>20 postulating potential non-causal explanations for</p> <p>21 associations.</p> <p>22 Q. You then go on to state in the next</p> <p>23 paragraph that "recollection bias should not be</p> <p>24 regarded as a likely explanation for the talc</p>	<p style="text-align: right;">Page 176</p> <p>1 what we decided on doing.</p> <p>2 MS. PARFITT: That is true.</p> <p>3 THE WITNESS: Forthcoming</p> <p>4 data -- it says:</p> <p>5 "Forthcoming data from the</p> <p>6 Nurses Health Study, a prospective cohort</p> <p>7 analysis, will relate ovarian cancer to</p> <p>8 talc habits queried before diagnosis.</p> <p>9 Until then, recollection bias should not</p> <p>10 be regarded as a likely explanation for</p> <p>11 the talc effect."</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. So what I read was a statement that</p> <p>14 was pending "forthcoming data from the Nurses</p> <p>15 Health Study," correct?</p> <p>16 A. I think the -- I think the idea here</p> <p>17 is there had never been a cohort study that had</p> <p>18 evaluated it, and there was the belief that --</p> <p>19 because at this -- when I wrote this, I didn't</p> <p>20 know what -- how the Nurses' Health Study had</p> <p>21 collected talc at that point.</p> <p>22 All we knew was that they were</p> <p>23 planning to do an analysis, and certainly we were</p> <p>24 all excited to see what that would find because it</p>
<p style="text-align: right;">Page 175</p> <p>1 effect."</p> <p>2 A. Hold on a second. The one that says</p> <p>3 "In the nine studies, the questions"? Is it that</p> <p>4 paragraph?</p> <p>5 Q. No. "In the nine studies," the very</p> <p>6 end of that paragraph.</p> <p>7 You wrote "recollection bias --</p> <p>8 A. Yes.</p> <p>9 Q. -- should not be regarded as a</p> <p>10 likely explanation for this talc effect."</p> <p>11 A. Yes.</p> <p>12 Q. Then related to the rest of that</p> <p>13 paragraph pending the results of "the Nurses</p> <p>14 Health Study, a prospective cohort analysis,"</p> <p>15 correct?</p> <p>16 MS. PARFITT: Objection.</p> <p>17 Misstates the article.</p> <p>18 THE WITNESS: I believe it</p> <p>19 says --</p> <p>20 MR. HEGARTY: Michelle, can we</p> <p>21 limit it to one person objecting?</p> <p>22 MS. PARFITT: No, no. That's</p> <p>23 okay.</p> <p>24 MR. HEGARTY: I think that's</p>	<p style="text-align: right;">Page 177</p> <p>1 was a cohort study.</p> <p>2 Q. Please look at the abstract on</p> <p>3 page 1.</p> <p>4 A. For my? Yes.</p> <p>5 Q. Of your 1995 publication.</p> <p>6 A. Yes.</p> <p>7 1990 -- oh, right. 1995. Yes. Got</p> <p>8 it.</p> <p>9 Q. If you look in the middle paragraph.</p> <p>10 A. Wait. Are we talking of the</p> <p>11 abstract or?</p> <p>12 Q. The abstract, yes.</p> <p>13 A. Okay. Yes. Uh-huh.</p> <p>14 Q. You do call that the abstract,</p> <p>15 right?</p> <p>16 A. Yes, yes, yes, yes. Sorry.</p> <p>17 Q. Okay. I'm just trying to use the</p> <p>18 term right.</p> <p>19 A. No, no, no. No.</p> <p>20 Q. You wrote:</p> <p>21 "The authors conclude that the range</p> <p>22 of relative risk estimates from epidemiology, 1 to</p> <p>23 1.8, is plausible, but that additional</p> <p>24 epidemiologic studies, especially prospective</p>

<p style="text-align: right;">Page 178</p> <p>1 investigations are needed."</p> <p>2 Did I read that correctly?</p> <p>3 A. You did.</p> <p>4 Q. Do you stand behind what you said</p> <p>5 back then?</p> <p>6 A. I do, with the caveat that they are</p> <p>7 prospective studies that are specifically designed</p> <p>8 to look at this particular exposure.</p> <p>9 Q. Back in 1995 when you wrote this,</p> <p>10 you wrote that prospective investigations are</p> <p>11 needed to assess this relative risk of 1.0 to 1.8,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. You made that statement in part</p> <p>15 because of concern about recall bias, correct?</p> <p>16 MR. TISI: Objection.</p> <p>17 THE WITNESS: Well, that's not</p> <p>18 the -- that's not the only reason.</p> <p>19 If -- if we have the</p> <p>20 opportunity to look at incidence as</p> <p>21 opposed to estimating to actually</p> <p>22 calculate incidence and incidence rate</p> <p>23 ratios as opposed to estimating the rate</p> <p>24 ratio with odds ratios, we always want to</p>	<p style="text-align: right;">Page 180</p> <p>1 MR. HEGARTY: I'm going to</p> <p>2 mark as Exhibit 13 the 2000 Gertig study.</p> <p>3 (Document marked for</p> <p>4 identification as Harlow Exhibit 13.)</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. Are you familiar with that study?</p> <p>7 A. I am.</p> <p>8 Q. One of the authors was your -- was</p> <p>9 also a plaintiffs' expert, as you are, and one of</p> <p>10 your prior colleagues, Dr. Daniel Cramer, correct?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: Well --</p> <p>13 MR. TISI: Objection. He was</p> <p>14 not an expert at this time.</p> <p>15 Go ahead.</p> <p>16 THE WITNESS: Yeah, I have no</p> <p>17 idea what his subject --</p> <p>18 MR. TISI: Objection to the</p> <p>19 preamble.</p> <p>20 THE WITNESS: Yeah.</p> <p>21 MR. TISI: Just ask the</p> <p>22 question, counsel.</p> <p>23 THE WITNESS: Yeah. Yes,</p> <p>24 Dr. Cramer is an author on this paper.</p>
<p style="text-align: right;">Page 179</p> <p>1 be able to do that under the assumption</p> <p>2 that the study is designed appropriately.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Understand, but my question was</p> <p>5 limited to that you made that statement at least</p> <p>6 in part because of the concern for recall bias,</p> <p>7 correct?</p> <p>8 MR. TISI: Objection. Asked</p> <p>9 and answered.</p> <p>10 THE WITNESS: Yeah. For a</p> <p>11 number of reasons, recall bias could be</p> <p>12 one of many reasons, and particularly for</p> <p>13 those who are more subject to recall bias</p> <p>14 such as less frequent exposure.</p> <p>15 MR. HEGARTY: Let's go off the</p> <p>16 record for a second.</p> <p>17 (Recess: 12:30 p.m. -</p> <p>18 12:31 p.m.)</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. The study that you reference, that</p> <p>21 being the Nurses' Health Study, was ultimately</p> <p>22 published in what we call the 2000 Gertig study;</p> <p>23 is that right?</p> <p>24 THE WITNESS: That's correct.</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Looking at the abstract.</p> <p>3 A. Yes.</p> <p>4 Q. About two-thirds down, that study</p> <p>5 reported or says:</p> <p>6 "We observed no overall association</p> <p>7 with ever use -- with ever talc use and epithelial</p> <p>8 ovarian cancer (multivariate relative risk 1.09;</p> <p>9 95% confidence interval 0.86 to 1.37) and no</p> <p>10 increase in risk of ovarian cancer with increasing</p> <p>11 frequency of use."</p> <p>12 Correct?</p> <p>13 MR. TISI: Objection.</p> <p>14 THE WITNESS: That's what</p> <p>15 they state.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Okay. Turn over to page --</p> <p>18 MR. TISI: Feel free to read</p> <p>19 the entire thing.</p> <p>20 THE WITNESS: No. I know this</p> <p>21 article very well.</p> <p>22 MR. TISI: Okay.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Please turn over to page 251.</p>



<p style="text-align: right;">Page 182</p> <p>1 A. Yes.</p> <p>2 Q. Under the section "Discussion."</p> <p>3 A. Yes.</p> <p>4 Q. First paragraph, second sentence,</p> <p>5 the authors write:</p> <p>6 "Because we ascertained talc</p> <p>7 exposure prior to case diagnosis, the possibility</p> <p>8 for recall bias, which has been raised as a</p> <p>9 potential explanation for previous positive</p> <p>10 findings in case-control studies, is eliminated,</p> <p>11 and selection bias is reduced."</p> <p>12 That was a correct statement,</p> <p>13 correct?</p> <p>14 A. No, I don't necessarily believe that</p> <p>15 it was completely eliminated. The Nurses' Health</p> <p>16 Study was not designed specifically to look at</p> <p>17 women -- they were not enrolled into the study</p> <p>18 based on exposed or not exposed to talc and,</p> <p>19 therefore, all women in that study were required</p> <p>20 to recall their talc exposure.</p> <p>21 Q. You said you're familiar with this</p> <p>22 study?</p> <p>23 A. Yes.</p> <p>24 Q. You cannot conclude just by this</p>	<p style="text-align: right;">Page 184</p> <p>1 of just this study that there is an association</p> <p>2 between talc use and epithelial ovarian cancer --</p> <p>3 MR. TISI: Objection.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. -- correct?</p> <p>6 MR. TISI: Objection.</p> <p>7 Misstates testimony. Asked and answered.</p> <p>8 THE WITNESS: Well, actually,</p> <p>9 once they limited it to those who had not</p> <p>10 had a tubal ligation or hysterectomy, the</p> <p>11 overall association was 1.15 with a</p> <p>12 confidence interval of 0.9 to 1.5.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. With regard to that answer, staying</p> <p>15 with page 251.</p> <p>16 A. Yes.</p> <p>17 Q. Right-hand column, middle paragraph.</p> <p>18 A. Yes.</p> <p>19 Q. The authors write:</p> <p>20 "The potential effect of talc on the</p> <p>21 ovaries depends on migration of talc fibers</p> <p>22 through a patent genital tract, and we would,</p> <p>23 therefore, expect a stronger association among</p> <p>24 women without a tubal ligation who had used talc.</p>
<p style="text-align: right;">Page 183</p> <p>1 study that there is an association between talc</p> <p>2 use and ovarian cancer, correct?</p> <p>3 MR. TISI: Objection.</p> <p>4 THE WITNESS: No, that's</p> <p>5 not -- that's not true at all.</p> <p>6 Because as I stated, as I</p> <p>7 stated in my report, that they also</p> <p>8 reported an estimated risk ratio of 1.4</p> <p>9 for evasive serous ovarian tumors, which</p> <p>10 we know account for the large majority of</p> <p>11 ovarian cancer; and that when the</p> <p>12 analysis was restricted to women who are</p> <p>13 45 years of age or older in 1992, they</p> <p>14 might represent those who are more highly</p> <p>15 exposed and maybe possibly have something</p> <p>16 to do with asbestos contamination, the</p> <p>17 association was -- was present.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. My question was limited to ovarian</p> <p>20 cancer. So let me restate it.</p> <p>21 You cannot conclude on this study</p> <p>22 that there is an association -- let me start over</p> <p>23 again.</p> <p>24 You cannot conclude from the results</p>	<p style="text-align: right;">Page 185</p> <p>1 However, no effect modification was seen by</p> <p>2 history of tubal ligation."</p> <p>3 That's what they concluded, correct?</p> <p>4 A. Well, then it goes on to say:</p> <p>5 "Because we did not have the date of</p> <p>6 tubal ligation, some women may have begun talc use</p> <p>7 only after tubal ligation, potentially resulting</p> <p>8 in misclassification of talc use and attenuation</p> <p>9 of the relative risks."</p> <p>10 Q. But ultimately in their study, as</p> <p>11 they report here, when comparing women with tubal</p> <p>12 ligation and without tubal ligation, they found no</p> <p>13 statistically different results, correct?</p> <p>14 MR. TISI: Objection.</p> <p>15 THE WITNESS: Well, they did</p> <p>16 not find a statistically significant</p> <p>17 difference, but it doesn't -- but that</p> <p>18 doesn't take into account the amount of</p> <p>19 exposure that they had prior to or after</p> <p>20 the tubal ligation.</p> <p>21 So it's -- it doesn't -- if</p> <p>22 you're getting at whether -- if you're</p> <p>23 getting at the issue of patency, it</p> <p>24 doesn't adequately assess that.</p>



<p style="text-align: right;">Page 186</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Look back again at the abstract.</p> <p>3 A. Yes.</p> <p>4 Q. Particularly the part that I read to</p> <p>5 you that begins "We observed no overall</p> <p>6 association."</p> <p>7 Do you remember that part I read?</p> <p>8 A. Yes. Yes.</p> <p>9 Q. Is it your opinion that this study</p> <p>10 does show an overall association with ever talc</p> <p>11 use and epithelial ovarian cancer?</p> <p>12 A. It all depends on how you define an</p> <p>13 association. There is an elevated risk. It has a</p> <p>14 confidence interval that does include 1.</p> <p>15 Q. Understood.</p> <p>16 My question, though, is: Is it your</p> <p>17 opinion that this study does show an association</p> <p>18 with ever talc use and epithelial ovarian cancer?</p> <p>19 A. I would say, yes, it does when you</p> <p>20 take into account the refinement of the exposure</p> <p>21 assessment.</p> <p>22 Q. So in your opinion, the statement</p> <p>23 they make, "We observed no overall association</p> <p>24 with ever talc use and epithelial ovarian cancer,"</p>	<p style="text-align: right;">Page 188</p> <p>1 But just because the -- the odd --</p> <p>2 just because the 95 percent confidence interval</p> <p>3 includes 1 does not preclude that the association</p> <p>4 is going to be 1 or less. It all really depends</p> <p>5 on the -- on the -- on the width of the confidence</p> <p>6 interval to get a better sense of where the</p> <p>7 estimate likely falls.</p> <p>8 Q. Please turn over to page 18 of your</p> <p>9 expert report.</p> <p>10 A. 18 of my expert report.</p> <p>11 Q. What we marked as Exhibit Number 5.</p> <p>12 A. Yes.</p> <p>13 Q. At the end of that carryover</p> <p>14 paragraph just before the "Case-control studies</p> <p>15 are inferior to cohort study" section.</p> <p>16 Are you with me?</p> <p>17 A. Yeah. Let me just see. This is</p> <p>18 recall bias. Uh-huh.</p> <p>19 Q. It is in the recall bias section,</p> <p>20 correct?</p> <p>21 A. Yes, uh-huh. Uh-huh.</p> <p>22 Q. You say at the end of that section:</p> <p>23 "In our opinion, daily use of talc</p> <p>24 over long periods or decades is unlikely to be</p>
<p style="text-align: right;">Page 187</p> <p>1 is not correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 THE WITNESS: It's not a yes</p> <p>4 or no type of response. It's how one</p> <p>5 might interpret it.</p> <p>6 They interpreted it as showing</p> <p>7 no association based on a statistical cut</p> <p>8 point.</p> <p>9 My view is to look at the</p> <p>10 entire body of the article to try to get</p> <p>11 a sense of whether or not there is an</p> <p>12 association under the appropriate exposed</p> <p>13 situations.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. For purposes of your report and your</p> <p>16 testimony in this case, how are you defining the</p> <p>17 phrase "an association"? What's your definition?</p> <p>18 A. An association in my -- would be my</p> <p>19 definition that shows that the risk estimate is</p> <p>20 more likely to be positive than not.</p> <p>21 When the odds -- when the odds ratio</p> <p>22 or relative risk does not include 1, then there is</p> <p>23 a much more certainty that the true association is</p> <p>24 greater than 1.</p>	<p style="text-align: right;">Page 189</p> <p>1 recalled inaccurately."</p> <p>2 Do you see where I'm reading?</p> <p>3 A. Actually, hold on a second.</p> <p>4 (Reviews document.)</p> <p>5 Yes. Okay. "In our opinion." Yes.</p> <p>6 Go ahead.</p> <p>7 Q. Is it your opinion that reporting of</p> <p>8 two times a week is also unlikely to be recalled</p> <p>9 inaccurately?</p> <p>10 A. Again, you're trying to make a</p> <p>11 dichotomy here.</p> <p>12 Certainly daily use of talc over</p> <p>13 long periods of time is not likely to be recalled</p> <p>14 inaccurately.</p> <p>15 I cannot speak to one -- to once a</p> <p>16 week or -- or once a month, but certainly the</p> <p>17 amount of recall bias, in my view, would increase</p> <p>18 with the -- with a decrease in frequency of using</p> <p>19 it.</p> <p>20 Q. Have you spoken with any of your</p> <p>21 colleagues at Boston University about your work on</p> <p>22 this litigation?</p> <p>23 A. No.</p> <p>24 Q. Have you told any of your colleagues</p>

<p style="text-align: right;">Page 190</p> <p>1 at Boston University your opinions in this  2 litigation as set out in your report?  3 A. No, I have not.  4 Q. Have you gone over to talk to any of  5 the gynecologists and gynecologic oncologists at  6 the Boston University Chobanian &amp; Avedisian --  7 A. (Laugh). Avedisian.  8 Q. -- Medical School of your opinions  9 in your report?  10 A. No, I have not.  11 Q. Have you talked to anyone at the  12 Boston University BMC Cancer Center about your  13 opinions in this report?  14 A. No, I have not.  15 Q. Have you told --  16 MR. TISI: I assume other than  17 Dr. Rothman, right?  18 MR. HEGARTY: Well, I'll let  19 him answer.  20 MR. TISI: Well, I mean, I'm  21 assuming that that's --  22 BY MR. HEGARTY:  23 Q. Well, Dr. Rothman, is he at the BU  24 BMC Cancer Center?</p>	<p style="text-align: right;">Page 192</p> <p>1 organizations or societies about your opinions in  2 this case?  3 A. I have not.  4 Q. Have you shared your opinions in  5 your report as to talc and ovarian cancer in any  6 written peer-reviewed publication?  7 MR. TISI: Objection.  8 THE WITNESS: Yeah. I don't  9 believe I have.  10 BY MR. HEGARTY:  11 Q. Have you shared your opinions set  12 out in your report at any symposia or conference?  13 A. No.  14 Q. And as I mentioned just a moment  15 ago, your report has not been peer-reviewed,  16 correct?  17 A. That is correct.  18 Q. Has any medical society or  19 organization reached out to you about talc and  20 ovarian cancer?  21 A. No.  22 Q. Can you cite to any U.S. scientific  23 or medical group, entity, or organization who has  24 made the statement that talc use can cause ovarian</p>
<p style="text-align: right;">Page 191</p> <p>1 A. No. He's in the School of Public  2 Health with me.  3 MR. HEGARTY: My question was  4 very specific. I said Boston University  5 BMC Cancer Center.  6 MR. TISI: Okay. Yeah. Got  7 it. Yeah.  8 BY MR. HEGARTY:  9 Q. Have you told any doctor treating  10 patients for ovarian cancer about your opinions in  11 this litigation?  12 A. I have not.  13 Q. Have you communicated with anyone  14 outside of plaintiffs' lawyers and Dr. Rothman  15 about your opinions in this case?  16 A. No.  17 Q. Have you talked to any scientific  18 body or group about your opinions in your report?  19 A. No.  20 Q. Has any regulatory authority or  21 scientific body reached out to you about your  22 opinions in the last 30 years?  23 A. No.  24 Q. Have you contacted any medical</p>	<p style="text-align: right;">Page 193</p> <p>1 cancer?  2 MR. TISI: Objection.  3 THE WITNESS: I am not aware  4 of a -- of a society or organization, as  5 you said, that specifically said talc  6 will cause ovarian cancer that I'm aware  7 of.  8 BY MR. HEGARTY:  9 Q. Are you aware of any gynecologic  10 oncologist, outside of any witness hired by the  11 plaintiffs in this litigation, who has stated that  12 talc use can cause ovarian cancer?  13 A. I wouldn't be able. I would have no  14 idea.  15 Q. Have you discussed your report or  16 your opinions in this case with any other experts  17 retained by plaintiffs' counsel in this  18 litigation --  19 A. As I --  20 Q. -- other than Dr. Rothman?  21 A. Yeah, I have not.  22 Q. Your list of Materials Considered  23 includes a reference to Dr. Longo's and Rigler's  24 February 2019 expert report.</p>

<p style="text-align: right;">Page 194</p> <p>1 Do you recall that?</p> <p>2 A. Yes, I do.</p> <p>3 Q. You also cite in your report to a</p> <p>4 study or -- sorry -- to a -- to a study or article</p> <p>5 by Steffen from 2020.</p> <p>6 Do you recall that article?</p> <p>7 A. Where do I cite that?</p> <p>8 Q. You include it in your references in</p> <p>9 the back and you cite to it in your report.</p> <p>10 Do you see that?</p> <p>11 A. Oh. Oh, right. Yes. Yes, yes,</p> <p>12 yes.</p> <p>13 Q. Particularly in your report on</p> <p>14 page 9.</p> <p>15 A. Yeah, yeah, yeah. Yes.</p> <p>16 I'm just looking where I cited it.</p> <p>17 Yes.</p> <p>18 MR. HEGARTY: And just so you</p> <p>19 can familiarize yourself with what I'm</p> <p>20 asking you, I'll mark as Exhibit 14 the</p> <p>21 Steffen article.</p> <p>22 (Document marked for</p> <p>23 identification as Harlow Exhibit 14.)</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 196</p> <p>1 Q. Did you note when you read it the</p> <p>2 disclosure or declaration of conflict of interest</p> <p>3 at the bottom of the first page?</p> <p>4 A. No, I didn't.</p> <p>5 Q. If you look at the bottom on the</p> <p>6 left-hand side, do you see where it says as it</p> <p>7 relates to certain of the authors, including</p> <p>8 Dr. Egilman -- well, let me start over again.</p> <p>9 As it relates to Dr. Egilman, that</p> <p>10 he serves as an expert witness in litigation at</p> <p>11 the request of people who are injured as a result</p> <p>12 of using talcum powder?</p> <p>13 A. Right.</p> <p>14 Q. Have you seen that before right now?</p> <p>15 A. Yeah. Right. Yes.</p> <p>16 Q. Had you seen that before right now?</p> <p>17 A. Oh, I probably saw it, but I don't</p> <p>18 necessarily evaluate literature based on -- based</p> <p>19 on this.</p> <p>20 Q. Do you see just below that part</p> <p>21 where it says:</p> <p>22 "Dr. Egilman, Dr. Rigler and</p> <p>23 Dr. Longo report payments from lawyers --</p> <p>24 A. Yes, I see it.</p>
<p style="text-align: right;">Page 195</p> <p>1 Q. That's the article --</p> <p>2 A. Yeah.</p> <p>3 Q. -- you reference in your report,</p> <p>4 correct?</p> <p>5 A. Just trying to see where I reference</p> <p>6 this article.</p> <p>7 Q. Please look over on page 9 in</p> <p>8 reference 7 at the top.</p> <p>9 A. Do I have it as reference 9 on my --</p> <p>10 let me -- let me just take a second. Hold on. Is</p> <p>11 it 7 or is it 9?</p> <p>12 Q. I'm looking at page 9 at the top.</p> <p>13 A. Oh, yeah. It's 7. Oh, yeah. Okay.</p> <p>14 Got it. Got it. Yes.</p> <p>15 Q. And reference 7 is Steffen's?</p> <p>16 A. Yes. Yes, yes, yes.</p> <p>17 Q. And I'm --</p> <p>18 A. Right. Right, right, right. Got</p> <p>19 it.</p> <p>20 Q. I marked as Exhibit Number 14 the</p> <p>21 Steffen's article.</p> <p>22 A. Yes.</p> <p>23 Q. Did you read this article?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 197</p> <p>1 Q. -- related to the submitted work"?</p> <p>2 A. Yes, I see it.</p> <p>3 Q. Did you consider that funding</p> <p>4 statement in evaluating this paper?</p> <p>5 A. No, I didn't.</p> <p>6 Q. Is it appropriate when you consider</p> <p>7 a paper like this to consider the source of</p> <p>8 funding and whether they're -- the authors are</p> <p>9 expert witnesses in litigation?</p> <p>10 A. I think it is important to consider</p> <p>11 it as one consideration, but I believe in this</p> <p>12 situation where -- where basically they are doing</p> <p>13 a laboratory assessment, I'm less concerned about</p> <p>14 whether or not that would have influenced the</p> <p>15 fundings.</p> <p>16 Q. The only authorities that you cite</p> <p>17 for the statements in your report that talcum</p> <p>18 powder contains asbestos are Dr. Longo and</p> <p>19 Rigler's report and the Steffen's article,</p> <p>20 correct?</p> <p>21 MR. TISI: Objection.</p> <p>22 THE WITNESS: Well, it's in my</p> <p>23 report, but in all my writings that I've</p> <p>24 published, I've -- I've referenced many</p>

<p style="text-align: right;">Page 198</p> <p>1 other articles.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. And I'm not asking about your other</p> <p>4 writings.</p> <p>5 A. I understand that.</p> <p>6 Q. My question is specific --</p> <p>7 specifically limited to your report.</p> <p>8 In your report --</p> <p>9 A. Yes.</p> <p>10 Q. -- the only authorities that you</p> <p>11 cite to for your statements that talcum powder,</p> <p>12 including Johnson &amp; Johnson talcum powder,</p> <p>13 contains asbestos are the Rigler and Longo</p> <p>14 materials and the Steffen's article, correct?</p> <p>15 MR. TISI: Objection.</p> <p>16 Misstates.</p> <p>17 THE WITNESS: So I would have</p> <p>18 to look. In this particular paragraph,</p> <p>19 but there might be other locations in the</p> <p>20 report where I had referred to that, and</p> <p>21 I would have to look carefully about</p> <p>22 that.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. How long would that take you to</p>	<p style="text-align: right;">Page 200</p> <p>1 MR. HEGARTY: But let's not</p> <p>2 get into discussion.</p> <p>3 MR. TISI: Okay.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. How much time? Do you need more</p> <p>6 time?</p> <p>7 A. I would need more time to look</p> <p>8 specifically at every word that I wrote to see if</p> <p>9 there are other locations -- other places where I</p> <p>10 cited the issue of talc -- the issue of asbestos</p> <p>11 being seen in talc examples.</p> <p>12 Q. And if we have time, we can go back</p> <p>13 to this question.</p> <p>14 A. Okay.</p> <p>15 Q. With regard to your citation to the</p> <p>16 report by Dr. Longo and Rigler, did you read the</p> <p>17 entirety of that report?</p> <p>18 A. I would hope I read the most salient</p> <p>19 components of it. (Laugh).</p> <p>20 Q. Well, can you tell me today --</p> <p>21 A. Yeah.</p> <p>22 Q. -- if you read the entirety of it</p> <p>23 from page to page?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 199</p> <p>1 look?</p> <p>2 A. Just give me a minute. Let me see</p> <p>3 if they're listed, if I had things.</p> <p>4 Okay. I'll -- I'll -- I'll agree</p> <p>5 that that's -- these are the -- this is the</p> <p>6 report.</p> <p>7 MR. TISI: Objection.</p> <p>8 THE WITNESS: This is the</p> <p>9 evidence.</p> <p>10 MR. TISI: Actually -- all</p> <p>11 right. I don't want you to feel rushed.</p> <p>12 Okay? If you need to look, I mean, there</p> <p>13 is -- fine. I'll clean it up.</p> <p>14 THE WITNESS: No, that's</p> <p>15 fine.</p> <p>16 MR. TISI: I mean, you know</p> <p>17 that that's --</p> <p>18 MR. HEGARTY: You can ask that</p> <p>19 question.</p> <p>20 MR. TISI: You know that</p> <p>21 that's not true. You can't --</p> <p>22 MR. HEGARTY: I don't know</p> <p>23 that that's not true.</p> <p>24 MR. TISI: Really?</p>	<p style="text-align: right;">Page 201</p> <p>1 Q. As to Dr. Longo and Rigler's report,</p> <p>2 did you make a request for that report or was that</p> <p>3 sent to you?</p> <p>4 A. That was sent to me.</p> <p>5 Q. Are you aware that there are more --</p> <p>6 there are other experts who have issued reports</p> <p>7 and who have testified with regard to the testing</p> <p>8 of talcum powder for asbestos?</p> <p>9 MR. TISI: In the MDL and New</p> <p>10 Jersey, or no?</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. We'll limit it to the MDL and New</p> <p>13 Jersey cases.</p> <p>14 A. Yeah. No, I'm not aware of that.</p> <p>15 Except that I'm aware of articles in the</p> <p>16 scientific literature that have been published</p> <p>17 that have shown the contamination of talc with</p> <p>18 asbestos in each decade for the last 40 years.</p> <p>19 Q. Did you ask or make a request for</p> <p>20 defense expert reports addressing the issues of</p> <p>21 asbestos testing for talc and asbestos in talc?</p> <p>22 MR. TISI: Objection. In the</p> <p>23 MDL or in New Jersey where he's</p> <p>24 designated?</p>

<p style="text-align: right;">Page 202</p> <p>1 MR. HEGARTY: Or anywhere in</p> <p>2 any situation.</p> <p>3 MR. TISI: Well, there have</p> <p>4 been none in any case in which he's been</p> <p>5 involved. So until you name them, you</p> <p>6 can't expect him to know them.</p> <p>7 MR. HEGARTY: I didn't ask him</p> <p>8 that. I just asked him --</p> <p>9 MR. TISI: Well, no. I mean,</p> <p>10 come on.</p> <p>11 MR. HEGARTY: Chris, listen to</p> <p>12 my question. I'll ask the question</p> <p>13 again.</p> <p>14 MR. TISI: That's totally</p> <p>15 unfair.</p> <p>16 MR. HEGARTY: Listen to my</p> <p>17 question.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. My question is: Did you ask for any</p> <p>20 expert reports that have been issued from</p> <p>21 attorney -- from experts representing or</p> <p>22 testifying on behalf of Johnson &amp; Johnson that</p> <p>23 respond or address the issues of asbestos in talc</p> <p>24 in particular as it relates to testing of talc for</p>	<p style="text-align: right;">Page 204</p> <p>1 extent that there's been any reports by</p> <p>2 the defendant in this litigation.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. You can answer.</p> <p>5 MR. TISI: You can answer.</p> <p>6 THE WITNESS: No, I have not.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. As to Dr. Longo's report, it was not</p> <p>9 a peer-reviewed document, correct?</p> <p>10 A. I'm not sure whether it was</p> <p>11 peer-reviewed or not.</p> <p>12 Q. Do you -- have you ever met</p> <p>13 Dr. Longo or Dr. Rigler?</p> <p>14 A. No.</p> <p>15 Q. Do you know anything about their</p> <p>16 training, education, and experience?</p> <p>17 A. I do not.</p> <p>18 Q. Do you know how much money Dr. Longo</p> <p>19 has made testifying for plaintiffs in talcum</p> <p>20 powder litigation?</p> <p>21 A. I do not.</p> <p>22 Q. Is that something you're interested</p> <p>23 in knowing?</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 203</p> <p>1 asbestos?</p> <p>2 MR. TISI: Your question</p> <p>3 assumes facts not in evidence in this MDL</p> <p>4 or in New Jersey. So I object.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. You can answer.</p> <p>7 A. I would not have known whether those</p> <p>8 existed or not. So I would not have known to ask.</p> <p>9 Q. If such reports and testimony exist,</p> <p>10 are you interested in reviewing them?</p> <p>11 A. Yes.</p> <p>12 MR. TISI: When they become</p> <p>13 available.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Have you reviewed Dr. Longo or</p> <p>16 Dr. Rigler's testimony in any case involving</p> <p>17 talcum powder and either ovarian cancer or</p> <p>18 mesothelioma?</p> <p>19 A. No.</p> <p>20 Q. Do you agree that you have not done</p> <p>21 a comprehensive analysis of all the expert reports</p> <p>22 and expert witness testimony on the issue of</p> <p>23 asbestos in talcum powder?</p> <p>24 MR. TISI: Objection to the</p>	<p style="text-align: right;">Page 205</p> <p>1 Q. Do you know how many times that</p> <p>2 Dr. Longo has testified for plaintiffs that</p> <p>3 products contain asbestos, that is, talcum powder</p> <p>4 products contain asbestos based on his testing?</p> <p>5 A. No, I do not know. I do not know.</p> <p>6 Q. Have you ever visited Dr. Longo's</p> <p>7 labs?</p> <p>8 A. No.</p> <p>9 Q. Is it true, Doctor, that you're not</p> <p>10 knowledgeable about -- let me start over again.</p> <p>11 It is true, Doctor, that you are not</p> <p>12 knowledgeable about the reasonableness of the</p> <p>13 processes and procedures of any of the tests that</p> <p>14 Dr. Longo and Rigler conducted on any talc</p> <p>15 product, correct?</p> <p>16 A. I do not know what their parameters</p> <p>17 were in their laboratory testing.</p> <p>18 Q. You have no --</p> <p>19 A. Other than what was written in the</p> <p>20 document.</p> <p>21 Q. Besides what you read, you have no</p> <p>22 ability to say that Dr. Longo's methods in looking</p> <p>23 for and identifying asbestos are reliable,</p> <p>24 correct?</p>



<p style="text-align: right;">Page 206</p> <p>1 A. Actually, reliable means that it is</p> <p>2 -- means it's been shown over and over again.</p> <p>3 That's what reliability means, and the fact that</p> <p>4 there have been a number of articles in the</p> <p>5 scientific literature by well before any of the</p> <p>6 litigation began showing that there is the</p> <p>7 potential for asbestos contamination, to me that</p> <p>8 suggests that the work that's done by Longo is --</p> <p>9 is reliable.</p> <p>10 Q. Do you know what a cleavage fragment</p> <p>11 is?</p> <p>12 A. No.</p> <p>13 Q. Can tremolite come in an asbestiform</p> <p>14 and non-asbestiform mineral type?</p> <p>15 A. I am not an expert in that area.</p> <p>16 Q. You're not an expert in asbestos?</p> <p>17 A. I would not call -- I am an expert</p> <p>18 in reviewing epidemiologic research, and I have</p> <p>19 the ability to look at research that has been in</p> <p>20 the peer-reviewed literature and make conclusions</p> <p>21 as to whether I believe they are scientifically</p> <p>22 strong or not.</p> <p>23 Q. Do you have an opinion as to whether</p> <p>24 non-asbestiform tremolite can cause ovarian</p>	<p style="text-align: right;">Page 208</p> <p>1 So, and talc itself has been shown to cause an</p> <p>2 inflammatory process.</p> <p>3 Q. Do your causation opinions in this</p> <p>4 litigation change at all if you concluded that</p> <p>5 there was no asbestos in talc?</p> <p>6 A. No, not necessarily.</p> <p>7 Q. Are you able to -- strike that.</p> <p>8 Do you have an opinion as to whether</p> <p>9 you can parse out what the effect is of asbestos</p> <p>10 in talc as relate to your causation opinions?</p> <p>11 A. No. For one thing, you just don't</p> <p>12 know.</p> <p>13 Q. There are six plaintiffs whose cases</p> <p>14 we are working up in the MDL and two plaintiffs in</p> <p>15 the -- in the New Jersey litigation.</p> <p>16 Let me give you their names and tell</p> <p>17 me after I'm finished whether you know any of</p> <p>18 these women.</p> <p>19 Lynda Bondurant, Escalina Roussa,</p> <p>20 Hilary Converse, Carter Judkins, Tamara Newsome,</p> <p>21 Anna Gallardo. And I'm not sure of the first</p> <p>22 names. I can look them up. Ms. Karl and</p> <p>23 Ms. Moldurano.</p> <p>24 Are any of those names familiar to</p>
<p style="text-align: right;">Page 207</p> <p>1 cancer?</p> <p>2 A. I don't have an opinion.</p> <p>3 Q. Sitting here today, can you name the</p> <p>4 six types of asbestos?</p> <p>5 A. No.</p> <p>6 Q. Do you know the most common -- the</p> <p>7 most commonest asbestos that was used</p> <p>8 commercially?</p> <p>9 A. That's not where I spend my time</p> <p>10 reviewing the scientific literature.</p> <p>11 The whole idea behind my review of</p> <p>12 the scientific literature was to determine whether</p> <p>13 there was a biologically plausible explanation for</p> <p>14 the epidemiologic association, and the fact that</p> <p>15 there is evidence that there could be asbestos</p> <p>16 contamination makes -- adds one more source of</p> <p>17 biological plausibility to it.</p> <p>18 Q. Is asbestos contamination of talc</p> <p>19 necessary for your causation opinions in this</p> <p>20 case?</p> <p>21 A. I don't believe so.</p> <p>22 Q. What -- I'm sorry.</p> <p>23 A. Certainly fibrous -- certainly</p> <p>24 fibrous talc could have -- could have an impact.</p>	<p style="text-align: right;">Page 209</p> <p>1 you?</p> <p>2 A. Not that I'm aware of, no.</p> <p>3 Q. Do you have any information about</p> <p>4 any of those women with regard to the type of</p> <p>5 ovarian cancer that they have?</p> <p>6 A. No.</p> <p>7 Q. Do you know where they live?</p> <p>8 A. No.</p> <p>9 Q. Do you know -- do you have any</p> <p>10 knowledge of any of the women whose names I just</p> <p>11 mentioned use of talcum powder?</p> <p>12 A. No.</p> <p>13 Q. In particular, do you know how long</p> <p>14 any of them used talcum powder?</p> <p>15 A. No.</p> <p>16 Q. Do you know the frequency that they</p> <p>17 used talcum powder?</p> <p>18 A. No.</p> <p>19 Q. Do you know the volume of talcum</p> <p>20 powder that they used?</p> <p>21 A. No.</p> <p>22 Q. Do you know if they used talcum</p> <p>23 powder in the genital area?</p> <p>24 A. No.</p>



<p style="text-align: right;">Page 210</p> <p>1 Q. Do you know of any testing for 2 asbestos that was done as to any talcum powder 3 product they claim to have used? 4 A. No. 5 Q. Are you going to tell the judge and 6 jury in the cases we're talking about today that 7 you know the cause of each of these women's 8 ovarian cancer? 9 MR. TISI: Objection. Can I 10 help you out and say he's not going to be 11 asked any questions about case-specific. 12 I'm not going to ask him. 13 MR. HEGARTY: Let him answer. 14 THE WITNESS: I can't answer 15 that. I have no idea what I'm going to 16 say. I have no idea at that point with 17 respect to that issue. 18 BY MR. HEGARTY: 19 Q. Well, let me ask it. 20 MR. TISI: He has not been 21 designated as a case-specific expert. 22 MR. HEGARTY: Let me re-ask 23 the question. 24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 212</p> <p>1 A. That is correct. 2 Q. Do you have any forthcoming 3 publications regarding talcum powder use and 4 ovarian cancer? 5 A. No. 6 Q. If you had any such publications or 7 if you have any such -- let me start over again. 8 If you have any publications in the 9 future, would you disclose as a conflict of 10 interest your work in this litigation? 11 A. Yes, I would if it was relevant to 12 this particular exposure and outcome. 13 Q. Are you working on any articles or 14 studies that pertain to talcum powder use and 15 ovarian cancer? 16 A. I am not. 17 Q. Are you working on any articles or 18 studies about asbestos and ovarian cancer? 19 A. No. 20 Q. Now, with regard to the report that 21 you and Dr. Rothman prepared in this litigation, 22 which we have been talking about this morning that 23 I marked as Exhibit Number 5 -- 24 A. Uh-huh.</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. Sitting here today, is it your 2 intent to tell the judge and the jury in this case 3 that you know what caused each of the women's 4 ovarian cancer whose names I read to you? 5 A. No. I -- all of -- what my 6 expertise is at the population level. I cannot -- 7 I cannot definitive -- I will not definitively 8 state that -- I don't know anything about these 9 women. I just don't know anything about these 10 women. 11 Q. Sitting here today, you don't 12 represent Boston University, correct? 13 A. That's correct. 14 Q. You don't speak for Boston 15 University or any entity in this case, correct? 16 A. I do not. 17 Q. You're not speaking for any 18 scientific organization or body? 19 A. No, I am not. 20 Q. You're not speaking for any 21 regulatory group or agency? 22 A. No. 23 Q. You're not speaking for anyone but 24 yourself?</p>	<p style="text-align: right;">Page 213</p> <p>1 Q. -- is it correct that all the 2 opinions that you intend to offer in this 3 litigation are set out in this report? 4 A. I believe so. Pending I believe at 5 the end of the report we had the -- we have the 6 right to look at additional information that 7 becomes available or provided to us. But barring 8 that, my opinions are in this report. 9 Q. Well, and you note at the end: 10 "We reserve the right to amend this 11 report." 12 You have not issued an amended 13 report, correct? 14 A. I have not. 15 Q. Have any of your opinions set out in 16 this report changed or modified since November 17 2023? 18 A. No. 19 Q. All the materials on which you 20 rely -- let me start over again. 21 All the materials on which you 22 intend to reference in providing your opinions are 23 set out in your report or in the Materials 24 Considered list, correct?</p>

<p style="text-align: right;">Page 214</p> <p>1 MR. TISI: Object. Objection.</p> <p>2 They may become.</p> <p>3 THE WITNESS: Well, I mean,</p> <p>4 again --</p> <p>5 MR. TISI: Additional --</p> <p>6 additional information -- one second.</p> <p>7 MR. HEGARTY: Please let him</p> <p>8 answer the question.</p> <p>9 MR. TISI: No, let me.</p> <p>10 Objection. He reserves the</p> <p>11 right and we reserve the right to ask him</p> <p>12 not only to comment on any expert report</p> <p>13 by the defendants, which has not been --</p> <p>14 they have not been provided yet, but also</p> <p>15 to respond to information that becomes</p> <p>16 available and have become available since</p> <p>17 the time of his report including, for</p> <p>18 example -- I mean, there are things like</p> <p>19 the recent EPA rule, for example.</p> <p>20 There are things that have</p> <p>21 become available and will continue to</p> <p>22 become available, and I expect him to be</p> <p>23 able to give opinions based upon those.</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 216</p> <p>1 communicating your opinions in this case?</p> <p>2 A. Again, I don't know.</p> <p>3 MR. TISI: Let me just object.</p> <p>4 I gave you an example, but I didn't mean</p> <p>5 that to be exclusive. There are things</p> <p>6 that we have provided to him or he's</p> <p>7 gotten on his own since the date of his</p> <p>8 report and now, and I can go through each</p> <p>9 and every one of them.</p> <p>10 I doubt you want me to do</p> <p>11 that, but I do not want that to --</p> <p>12 anything to be seen as we are limiting</p> <p>13 him to November of 2023, and I'm not</p> <p>14 going to do that.</p> <p>15 And there are going to be</p> <p>16 plenty. I mean, using your expert</p> <p>17 reports as an example. I reserve the</p> <p>18 right to ask him questions about things</p> <p>19 that are said in your expert reports, and</p> <p>20 I'm going to provide them to him.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. Can you answer my question?</p> <p>23 A. Would you repeat the question,</p> <p>24 please?</p>
<p style="text-align: right;">Page 215</p> <p>1 Q. Let me ask my question.</p> <p>2 Sitting here today, are all the</p> <p>3 materials you intend to refer to in providing your</p> <p>4 opinions in this case set out in your report</p> <p>5 either at the end of the report or in the</p> <p>6 Materials Considered list?</p> <p>7 A. No, I can't say that that's the case</p> <p>8 and --</p> <p>9 Q. Well, what materials -- I'm sorry.</p> <p>10 Go ahead.</p> <p>11 A. Well, the recent EPA report that</p> <p>12 came out that specified talc -- asbestos as being</p> <p>13 a cause for ovarian cancer is something that I</p> <p>14 might refer to, and I don't know what other</p> <p>15 information might come out from the scientific</p> <p>16 literature.</p> <p>17 So I can't affirmatively say that</p> <p>18 the only information that I might say in the</p> <p>19 future would come from articles and content in</p> <p>20 this report.</p> <p>21 Q. Other than the EPA report you</p> <p>22 referenced, do you know, sitting here today, of</p> <p>23 any other authority, publication, or otherwise you</p> <p>24 intend to refer to as of today in discussing or</p>	<p style="text-align: right;">Page 217</p> <p>1 Q. Sure.</p> <p>2 Sitting here today, other than the</p> <p>3 recent EPA report you referenced, do you know of</p> <p>4 any other references that you're going to refer to</p> <p>5 in providing your opinions in this case?</p> <p>6 MR. TISI: Objection for the</p> <p>7 reasons I stated.</p> <p>8 You may answer.</p> <p>9 THE WITNESS: I don't know</p> <p>10 what other references or documents that</p> <p>11 might become available at the time. So I</p> <p>12 can't say that I know of something as of</p> <p>13 right now.</p> <p>14 MR. HEGARTY: Let's go off the</p> <p>15 record.</p> <p>16 (Whereupon, at 1:04 p.m., a</p> <p>17 luncheon recess was taken.)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 218</p> <p>1 AFTERNOON SESSION</p> <p>2 (1:40 p.m.)</p> <p>3 BERNARD L. HARLOW, PHD</p> <p>4 called for continued examination and, having been</p> <p>5 previously duly sworn, was examined and testified</p> <p>6 further as follows:</p> <p>7 EXAMINATION (CONTINUED)</p> <p>8 MR. HEGARTY: We are back on</p> <p>9 the record after a short lunch break.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Doctor, do you agree that before</p> <p>12 offering opinions in a case like this, where you</p> <p>13 will be heard by and relied upon by a judge and a</p> <p>14 jury, you should have completed a comprehensive</p> <p>15 analysis of the literature that was available to</p> <p>16 you about the subject matter of your opinions?</p> <p>17 A. Yes.</p> <p>18 Q. Have you ever offered in any public</p> <p>19 published opinions -- let me start over again.</p> <p>20 Have you ever offered in any</p> <p>21 publication opinions on any subject matter that</p> <p>22 would be read and relied upon by your peers and</p> <p>23 others that was not based on a comprehensive</p> <p>24 analysis of the literature that was available to</p>	<p style="text-align: right;">Page 220</p> <p>1 A. I reviewed -- yes, there are reviews</p> <p>2 that I -- I cited in my previous publications</p> <p>3 and -- but, again, I was -- I was focusing on the</p> <p>4 epidemiologic human studies with respect to coming</p> <p>5 up with my opinions.</p> <p>6 Q. Do you agree that you did not</p> <p>7 specifically cite to any animal study in your</p> <p>8 report?</p> <p>9 A. I --</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: I -- I can't be</p> <p>12 certain of that, but it certainly did not</p> <p>13 weigh in on my conclusions.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Did you do a comprehensive review of</p> <p>16 all the cell study literature involving talcum</p> <p>17 powder?</p> <p>18 A. No.</p> <p>19 Q. You did not refer to any cell</p> <p>20 studies where cells are or talc has been applied</p> <p>21 to cells in your report, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Did you do a comprehensive analysis</p> <p>24 of all the publications that have discussed</p>
<p style="text-align: right;">Page 219</p> <p>1 you on the subject matter of the whatever you were</p> <p>2 discussing?</p> <p>3 A. No.</p> <p>4 Q. With regard to what you reviewed for</p> <p>5 your opinions in your report, did you do a</p> <p>6 comprehensive analysis of all the animal studies</p> <p>7 involving talcum powder?</p> <p>8 MR. TISI: Objection. Vague.</p> <p>9 THE WITNESS: I reviewed some</p> <p>10 of the animal models, but the problem is</p> <p>11 that it's -- it's difficult because most</p> <p>12 of the studies have been done in mice and</p> <p>13 rats, and they have different anatomical</p> <p>14 features that are dissimilar from that</p> <p>15 with women, such as a bursa sac that</p> <p>16 encloses the ovaries.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. In connection with preparing your</p> <p>19 report in this case, did you review the studies of</p> <p>20 those animal models?</p> <p>21 A. No, I didn't.</p> <p>22 Q. So any review of the animal studies</p> <p>23 that you referenced was before you were contacted</p> <p>24 by plaintiffs' counsel?</p>	<p style="text-align: right;">Page 221</p> <p>1 asbestos and ovarian cancer?</p> <p>2 A. No, I did not.</p> <p>3 Q. As to the IARC 2012 Monograph, which</p> <p>4 you do reference in your report --</p> <p>5 A. Uh-huh.</p> <p>6 Q. -- did you read that monograph when</p> <p>7 it came out initially?</p> <p>8 A. No.</p> <p>9 Q. Did you read that monograph before</p> <p>10 you started working on your expert report?</p> <p>11 A. No.</p> <p>12 Q. Did you read the entirety of that</p> <p>13 monograph in connection with preparing your expert</p> <p>14 report?</p> <p>15 A. I read parts of it.</p> <p>16 Q. That monograph referred to a number</p> <p>17 of studies that looked at asbestos exposure and</p> <p>18 ovarian cancer.</p> <p>19 Did you pull the individual studies</p> <p>20 and read them --</p> <p>21 A. I didn't.</p> <p>22 Q. -- that were referenced in the</p> <p>23 monograph?</p> <p>24 A. No, I didn't. Again, that goes</p>

<p style="text-align: right;">Page 222</p> <p>1 toward biological plausibility, and I felt there</p> <p>2 was a lot of evidence already for biological</p> <p>3 plausibility that I didn't need to do an</p> <p>4 exhaustive literature search on the association</p> <p>5 between asbestos and ovarian cancer.</p> <p>6 Q. Do you have an opinion for purposes</p> <p>7 of this case as to the level of exposure to</p> <p>8 asbestos that is necessary to cause ovarian</p> <p>9 cancer?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: I think any</p> <p>12 exposure to asbestos is important.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Is it your opinion that any level of</p> <p>15 exposure to asbestos can cause ovarian cancer?</p> <p>16 A. I'm not -- I didn't do a causal</p> <p>17 analysis around that, but I would certainly be</p> <p>18 worried about any asbestos contaminant -- any</p> <p>19 asbestos exposure and risk of ovarian cancer.</p> <p>20 Q. Do you have an opinion as to the</p> <p>21 types of asbestos that have been shown to cause</p> <p>22 ovarian cancer?</p> <p>23 A. No, I don't have an opinion there.</p> <p>24 MR. TISI: Sorry. Again, keep</p>	<p style="text-align: right;">Page 224</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Yeah. My question is: Are you</p> <p>3 aware of either from your own reading or from</p> <p>4 other sources hearing that there are background</p> <p>5 rates of asbestos in certain parts of the United</p> <p>6 States?</p> <p>7 A. I have not read that.</p> <p>8 Q. Do you have any opinion as to</p> <p>9 whether background rates of asbestos just in the</p> <p>10 air are capable of causing ovarian cancer?</p> <p>11 A. I don't have an opinion around that.</p> <p>12 Q. Do you agree that there are exposure</p> <p>13 levels to asbestos where no harm has been shown?</p> <p>14 A. I'm not aware of that.</p> <p>15 And I certainly have not heard any</p> <p>16 regulatory body suggesting that there is a certain</p> <p>17 acceptable level of asbestos.</p> <p>18 Q. Did you do any analysis in your</p> <p>19 report as to the biologic plausibility of asbestos</p> <p>20 fibers causing ovarian cancer?</p> <p>21 A. Could you repeat that, please?</p> <p>22 Q. Sure.</p> <p>23 Did you do any analysis as set out</p> <p>24 in your report of the biologic plausibility of</p>
<p style="text-align: right;">Page 223</p> <p>1 your voice up.</p> <p>2 THE WITNESS: Sorry. Let me</p> <p>3 know if you're not hearing me.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Are you aware of any literature --</p> <p>6 published literature that has stated that asbestos</p> <p>7 in talc applied to the genital area can cause</p> <p>8 ovarian cancer, that the route of delivery of</p> <p>9 asbestos via talc can cause ovarian cancer?</p> <p>10 MR. TISI: Objection.</p> <p>11 THE WITNESS: Yeah. I have</p> <p>12 not seen those words used, but I have</p> <p>13 seen many articles where it is</p> <p>14 hypothesized that asbestos contamination</p> <p>15 of talc is a biological mechanism by</p> <p>16 which ovarian cancer -- by which ovarian</p> <p>17 cancer could occur.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Have you ever read studies or become</p> <p>20 aware of studies reporting that there are</p> <p>21 background rates of asbestos in certain areas of</p> <p>22 this country?</p> <p>23 MR. TISI: I'm sorry.</p> <p>24 Rephrase. I mean, repeat it.</p>	<p style="text-align: right;">Page 225</p> <p>1 asbestos fibers causing ovarian cancer?</p> <p>2 A. In my report, I did not dissociate</p> <p>3 whether my view on the cause of ovarian cancer is</p> <p>4 limited to that exposure which is contaminated</p> <p>5 with asbestos.</p> <p>6 Q. Do you have any opinion as to the</p> <p>7 exposure levels or dose of asbestos necessary to</p> <p>8 be biologically plausible -- to be a biologically</p> <p>9 plausible cause of ovarian cancer?</p> <p>10 MR. TISI: Objection. Let me</p> <p>11 just put my objection on the record.</p> <p>12 Biologically plausible cause</p> <p>13 are inconsistent.</p> <p>14 THE WITNESS: Could you</p> <p>15 please repeat?</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Sure.</p> <p>18 Do you have any opinion as to what</p> <p>19 exposure levels or dose of asbestos is necessary</p> <p>20 to have biologic plausibility between ovarian</p> <p>21 cancer and asbestos exposure?</p> <p>22 MR. TISI: Objection.</p> <p>23 THE WITNESS: Yeah. In my</p> <p>24 view, any amount of asbestos</p>

<p style="text-align: right;">Page 226</p> <p>1 contamination is of concern to me.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. Do you have any opinion as to the</p> <p>4 volume of asbestos that's been -- that has been in</p> <p>5 Johnson's Baby Powder or Shower to Shower over the</p> <p>6 years?</p> <p>7 A. Could you repeat the question again?</p> <p>8 Q. Sure.</p> <p>9 Do you have any opinion as to the</p> <p>10 volume of asbestos fibers in Johnson's Baby Powder</p> <p>11 or Shower to Shower over the last 70 years?</p> <p>12 A. Yeah. Only -- only that over many</p> <p>13 decades asbestiform fibers have been observed in</p> <p>14 the talc products. The volume is -- I don't know</p> <p>15 how -- well, it's -- I have not -- I have no</p> <p>16 opinion about what volume is necessary to make it</p> <p>17 a risk factor. Only that it has consistently been</p> <p>18 shown to be present.</p> <p>19 Q. Do you know what percentage --</p> <p>20 strike that.</p> <p>21 Do you have an opinion as to what</p> <p>22 percentage of Johnson's Baby Powder and Shower to</p> <p>23 Shower bottles manufactured over the years have</p> <p>24 contained any amount of asbestos?</p>	<p style="text-align: right;">Page 228</p> <p>1 But I do want to just clarify that</p> <p>2 talc particulates have been observed both in the</p> <p>3 fallopian tubes and in the ovaries.</p> <p>4 Q. My question is a little bit</p> <p>5 different.</p> <p>6 Can you cite for me any studies that</p> <p>7 have focused on the fallopian tube with regard to</p> <p>8 talc when discussing biologic plausibility?</p> <p>9 A. Only to the extent that -- only to</p> <p>10 the extent that exposure in the fallopian tubes is</p> <p>11 sufficient to, along -- along with -- with actual</p> <p>12 exposure within the ovaries, is sufficient to</p> <p>13 warrant biological plausibility.</p> <p>14 Q. You recall the authors on any of --</p> <p>15 any such study that have talked about that?</p> <p>16 A. I believe it's possible that</p> <p>17 Silkraut might have talked about that.</p> <p>18 Q. You mean Schildkraut?</p> <p>19 A. Yeah, Schildkraut.</p> <p>20 Q. The study we talked about today?</p> <p>21 A. Yes. Yes. I believe that to be the</p> <p>22 case, as I recall.</p> <p>23 Q. With regard to your methodology for</p> <p>24 preparing the report --</p>
<p style="text-align: right;">Page 227</p> <p>1 A. I don't have any opinion on what</p> <p>2 proportion of products did and did not have</p> <p>3 contamination. Only that there is evidence to</p> <p>4 show that many did.</p> <p>5 Q. For purposes of your biologic</p> <p>6 plausibility opinion --</p> <p>7 A. Yes.</p> <p>8 Q. -- is it necessary for a talcum</p> <p>9 powder product to reach the ovaries?</p> <p>10 A. No. It could cause a carcinogenic</p> <p>11 process in the fallopian tubes. So it doesn't</p> <p>12 necessarily have to have been -- have to have</p> <p>13 reached the ovaries.</p> <p>14 And there's new evidence to suggest</p> <p>15 that certain epithelial ovarian cancers actually</p> <p>16 arise in the fallopian tubes.</p> <p>17 Q. Can you cite for me any studies that</p> <p>18 have commented on biologic plausibility as it</p> <p>19 relates to talc and ovarian cancer with regard to</p> <p>20 the ovarian -- with regard to the fallopian tubes</p> <p>21 versus the ovaries?</p> <p>22 A. I have read that some histologic</p> <p>23 subtypes may be more likely to initiate in the</p> <p>24 fallopian tubes as opposed to the ovaries.</p>	<p style="text-align: right;">Page 229</p> <p>1 A. Yes.</p> <p>2 Q. -- at the time you started this</p> <p>3 process, did you and Dr. Rothman share the same</p> <p>4 methodology?</p> <p>5 A. Yes. I have always used the</p> <p>6 criteria pointed out by Hill as factors to be</p> <p>7 considered but not solely determinant for making a</p> <p>8 causation assessment.</p> <p>9 Q. Can you cite for me any instances</p> <p>10 where you have set out in the published literature</p> <p>11 the methodology you employed in this case for</p> <p>12 analyzing whether talcum powder use can cause</p> <p>13 ovarian cancer?</p> <p>14 A. Well, I think in my earlier</p> <p>15 publications I followed a similar approach,</p> <p>16 looking at issues related to strength and</p> <p>17 consistency of the association, dose response when</p> <p>18 available, biological plausibility. But always</p> <p>19 taking into consideration biases that could</p> <p>20 explain the findings that we see with respect to</p> <p>21 confounding, misclassification, temporality.</p> <p>22 So -- even recall bias.</p> <p>23 So I would like to think that I have</p> <p>24 taken -- and, frankly, in reading my older</p>



<p style="text-align: right;">Page 230</p> <p>1 articles, I'm actually quite impressed that I</p> <p>2 followed those guidelines throughout my career.</p> <p>3 Q. When you're talking about your</p> <p>4 article, are you talking about the articles that</p> <p>5 you have been author on about talc and ovarian</p> <p>6 cancer?</p> <p>7 A. Yes. Yes.</p> <p>8 Q. Other than those articles, can you</p> <p>9 tell me any other publications of yours where you</p> <p>10 apply the same methodology as you applied in your</p> <p>11 report?</p> <p>12 A. Oh, virtually all of my articles</p> <p>13 that relate to the etiology of -- etiology of a</p> <p>14 particular adverse outcome.</p> <p>15 Q. Please look at page 4 of your</p> <p>16 report.</p> <p>17 The section "Overall Approach and</p> <p>18 Methodology of This Review" sets out your</p> <p>19 methodology for your analysis of the literature</p> <p>20 regarding talcum powder use and ovarian cancer,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. This part of your report refers to</p> <p>24 the Bradford-Hill analysis or criteria, but at the</p>	<p style="text-align: right;">Page 232</p> <p>1 MR. TISI: Let me just object</p> <p>2 to the word "criteria" because that's not</p> <p>3 what it says.</p> <p>4 THE WITNESS: There I believe</p> <p>5 what we tried to say is that there is no</p> <p>6 checklist alone that can be used for</p> <p>7 causal inference, and that's the first</p> <p>8 sentence of the -- of the next paragraph.</p> <p>9 "If no checklist for causal</p> <p>10 inference exists, then how does causal</p> <p>11 inference proceed?"</p> <p>12 And the way I believe we talk</p> <p>13 about it throughout the report is, we</p> <p>14 look at the components that are indicated</p> <p>15 as Bradford-Hill components, but always</p> <p>16 look at them in the context of how they</p> <p>17 could have been influenced by</p> <p>18 bias-related issues, and that's what we</p> <p>19 tried to -- to lay out here. So, yeah.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. So in this part of your report,</p> <p>22 you're not -- you're not saying that the</p> <p>23 Bradford-Hill analysis, factors, or criteria,</p> <p>24 however you want to characterize it, leads to an</p>
<p style="text-align: right;">Page 231</p> <p>1 end of the first paragraph you write:</p> <p>2 "Unfortunately, despite the fact</p> <p>3 that purported lists of causal criteria have been</p> <p>4 proposed and implemented, a valid set of such</p> <p>5 criteria does not exist."</p> <p>6 You see where I'm reading?</p> <p>7 A. Yes, I do.</p> <p>8 MR. TISI: Let me just object</p> <p>9 to your characterization as a criteria,</p> <p>10 but go ahead.</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. You then go on in the next two</p> <p>13 paragraphs to essentially say there is no</p> <p>14 checklist for causal inference, correct?</p> <p>15 A. Alone. (Nods head).</p> <p>16 Q. I read this summary as rejecting --</p> <p>17 or let me start over again.</p> <p>18 My interpretation of this section is</p> <p>19 that you are not applying the Bradford-Hill</p> <p>20 criteria but a criteria that, as you say, is</p> <p>21 focused on posing non-causal explanations to</p> <p>22 account for the association.</p> <p>23 Are you saying that you did apply in</p> <p>24 this report the Bradford-Hill criteria?</p>	<p style="text-align: right;">Page 233</p> <p>1 unreliable result?</p> <p>2 A. I think if you only do a checklist</p> <p>3 without taking into account how that data was</p> <p>4 obtained, then, yes, I believe the Bradford</p> <p>5 criteria do not in and of itself allow for a</p> <p>6 causal -- allow for causal inference.</p> <p>7 Q. So as an example, if you only talk</p> <p>8 about strength of association there being a</p> <p>9 relative risk or odds ratio that is considered to</p> <p>10 satisfy that analysis to be strong or without</p> <p>11 identifying or comparing the literature on whether</p> <p>12 that can be explained by other reasons, that would</p> <p>13 not be a valid result?</p> <p>14 A. That's correct. If I believe that a</p> <p>15 risk estimate of 1.5 could potentially be</p> <p>16 explained by confounding that was not considered</p> <p>17 or misclassification of the exposure that was</p> <p>18 being used to assess that and to calculate that</p> <p>19 particular estimate of risk, then I would not --</p> <p>20 just because it's a 1.5 with a confidence interval</p> <p>21 that includes 1.0 doesn't necessarily mean that I</p> <p>22 would believe that it meets the criteria for</p> <p>23 causation.</p> <p>24 I would have to have determined that</p>



<p style="text-align: right;">Page 234</p> <p>1 I can't come up with any other explanation for why  2 we see this association for me to then believe  3 that the magnitude of the association is  4 believable.</p> <p>5 Q. In your report, you don't walk  6 through and discuss each of the nine Bradford-Hill  7 factors or criteria, or however you called it,  8 that he set out in his statement, correct?</p> <p>9 A. That's correct.</p> <p>10 Q. For example, you don't talk about  11 temporality or experiment. All those other -- all  12 the factors, correct?</p> <p>13 A. I -- well, I don't talk about the  14 ones that are obviously in place. For example, I  15 don't think anybody would believe that ovarian  16 cancer leads one to initiate exposure to talc and  17 so, therefore, temporality I think seems  18 reasonably obvious.</p> <p>19 So we chose to focus on the ones  20 that were most contested by colleagues.</p> <p>21 Q. What are the ones that are most  22 contested that you focused on?</p> <p>23 A. Well, certainly the -- the magnitude  24 of the association, dose response where it could</p>	<p style="text-align: right;">Page 236</p> <p>1 A. I read the ones that I thought were  2 most appropriate. So, for example, case series I  3 did not put a lot of stock into. I looked at  4 certain commentaries to see whether or not they  5 were specifically addressing the issue of talc.</p> <p>6 So I was selective in looking at all  7 observational studies and, frankly, there hasn't  8 been any new data collection -- new primary data  9 collection from what I could tell since 2016. So  10 most of the literature that's been published since  11 then has been meta-analyses or reanalyses of  12 existing data.</p> <p>13 Q. In evaluating the studies either  14 from your own search or from what you otherwise  15 had or been provided, did you assess the strengths  16 and weaknesses in each paper?</p> <p>17 A. I believe I did.</p> <p>18 Q. Did you assign a weight or a  19 numerical value to the -- to each paper?</p> <p>20 A. No. No, I did not. I -- unless --  21 well, I looked at each paper as its own  22 contribution and what the strengths and  23 limitations were and made a decision on its  24 scientific validity.</p>
<p style="text-align: right;">Page 235</p> <p>1 be occurred -- would occur, the biological  2 plausibility, the consistency of the findings  3 across studies. Those are certainly the ones that  4 we focused on mostly and, in particular, how the  5 assessment of the exposure could have influenced  6 all of those factors.</p> <p>7 Q. You mentioned early on in the  8 deposition that you did your own literature  9 search, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Did anyone assist you in doing that?</p> <p>12 A. No.</p> <p>13 Q. What literature engines or tools did  14 you use?</p> <p>15 A. I used PubMed, Medline.</p> <p>16 Q. Did you prepare in advance a  17 protocol for how you were going to research the  18 literature?</p> <p>19 A. No, but I've been researching  20 literature for an awful long time. (Laugh). I  21 don't think I need a protocol at this point.</p> <p>22 Q. With regard to the materials you  23 identified from that literature search, did you  24 read them all in their entirety?</p>	<p style="text-align: right;">Page 237</p> <p>1 I didn't say this one gets ranked as  2 a 10; this one gets ranked as a 5. Instead, I  3 looked at those that were obviously flawed in my  4 view versus those that, after an extensive review  5 of the data that was available, I felt that the  6 findings were believable.</p> <p>7 Q. As of the time you started this  8 process in preparing your report, had you read all  9 of the case-control studies on talc and ovarian  10 cancer?</p> <p>11 A. No, I hadn't.</p> <p>12 Q. At the time you started this process  13 of preparing your expert report, had you read all  14 the cohort studies on talc and ovarian cancer?</p> <p>15 A. I believe I had read the Gertig one  16 in the past, but the one from the Sister Study and  17 the one from the WHI I hadn't read.</p> <p>18 Q. Had you read the O'Brien 2020  19 meta-analysis or pooled analysis of the four  20 cohorts before you were contacted by plaintiffs'  21 counsel -- by plaintiffs' counsel about  22 participating in this litigation as an expert?</p> <p>23 A. Yes, I did.</p> <p>24 Q. Had you read all the meta-analyses</p>

<p style="text-align: right;">Page 238</p> <p>1 regarding talc and ovarian cancer prior to 2 starting this process of preparing your expert 3 report? 4 A. No, I did not. 5 Q. In particular, had you read 6 Penninkilampi before you started this process? 7 A. Yeah. No. 8 Q. Had you read Taher before you 9 started this process? 10 A. No. 11 Q. Had you read Berge before you 12 started this process? 13 A. No, I hadn't. 14 Q. As part of your work on this case, 15 have you reviewed any documents, that is internal 16 documents, produced by Johnson &amp; Johnson? 17 A. No, not that I'm aware of. 18 Q. In particular as to the documents 19 produced by Johnson &amp; Johnson, have you reviewed 20 -- have you reviewed any of the asbestos testing 21 documents that Johnson &amp; Johnson has produced in 22 this case? 23 A. I -- I don't recall. I don't -- I 24 don't -- I don't recall.</p>	<p style="text-align: right;">Page 240</p> <p>1 Johnson &amp; Johnson has produced as part of this 2 case, have you reviewed any of them? 3 A. I have not that I'm aware of and I'd 4 love to. 5 Q. So would it be a fair statement 6 that, as of today, you have not done a 7 comprehensive analysis of the available asbestos 8 testing documents that have been provided in this 9 litigation? 10 MR. TISI: Objection. 11 Misstates his report. 12 THE WITNESS: Yeah, I've 13 reviewed. Anything that's been in the 14 scientific literature I've seen and the 15 Longo report that was provided to me. 16 BY MR. HEGARTY: 17 Q. But as far as the asbestos testing 18 documents that Johnson &amp; Johnson has produced in 19 this case, you have not reviewed? 20 A. No. 21 MR. TISI: Objection. 22 Let me just -- 23 THE WITNESS: Yeah. 24 MR. TISI: Let me just place</p>
<p style="text-align: right;">Page 239</p> <p>1 MR. TISI: Let me just clarify 2 this so you know. He was provided with 3 the Rothman report which came from the 4 litigation in this case, which was not 5 published. I just wanted to be clear on 6 that. That was -- that was a J&amp;J or PCPC 7 report. 8 MR. HEGARTY: I understand. 9 My question -- 10 THE WITNESS: Oh. 11 MR. HEGARTY: My question is 12 of the laboratory testing results. 13 MR. TISI: No, it was the 14 question before you asked. 15 MR. HEGARTY: Okay. 16 MR. TISI: Any documents 17 provided in the litigation. I just 18 wanted to. 19 MR. HEGARTY: Okay. I 20 apologize. 21 THE WITNESS: I -- yeah. 22 BY MR. HEGARTY: 23 Q. With regard to the talcum powder 24 testing documents, that is, for asbestos that</p>	<p style="text-align: right;">Page 241</p> <p>1 an objection. 2 Misstates his report. 3 BY MR. HEGARTY: 4 Q. You can answer. 5 A. To my knowledge, I have not seen 6 testing that was specifically done by Johnson &amp; 7 Johnson. 8 Q. You said you would like to see that. 9 Why would you like to see it? 10 A. Well, I'd like to see the methods 11 that they used. I'd like to compare them to the 12 way in which it was done by other -- by others. 13 I'd like to know whether the -- the limit of 14 detection was the same. I mean, I would want to 15 just basically evaluate it like any other 16 epidemiologist might. 17 Q. The testing that has been done with 18 regard to talc and asbestos includes such methods 19 as TEM, XRD, PLM. 20 Are you an expert in any of those 21 methods? 22 A. No, I'm not. 23 Q. Now, you reference in your report, 24 you make reference in your report to IARC and</p>

<p style="text-align: right;">Page 242</p> <p>1 Health Canada, correct?</p> <p>2 A. Yes, uh-huh.</p> <p>3 Q. Do you reference anywhere in your</p> <p>4 report any findings as -- by FDA as it relates to</p> <p>5 talc and ovarian cancer?</p> <p>6 MR. TISI: Objection.</p> <p>7 Objection.</p> <p>8 THE WITNESS: I don't believe</p> <p>9 I -- let me just think about this.</p> <p>10 Not --</p> <p>11 MR. TISI: If you need to look</p> <p>12 at your report --</p> <p>13 THE WITNESS: Yeah.</p> <p>14 MR. TISI: -- feel free to do</p> <p>15 that.</p> <p>16 THE WITNESS: (Reviews</p> <p>17 document.)</p> <p>18 MR. TISI: I mean, do you mind</p> <p>19 if -- so I could move it along and help</p> <p>20 you with this?</p> <p>21 MR. HEGARTY: Well, my</p> <p>22 question --</p> <p>23 MR. TISI: He does cite it in</p> <p>24 Section B.</p>	<p style="text-align: right;">Page 244</p> <p>1 has said with regard to talcum powder use and</p> <p>2 ovarian cancer in your report?</p> <p>3 A. I don't know if it was -- if I had</p> <p>4 that available at the time of writing the report.</p> <p>5 Q. When you say you had "that," you're</p> <p>6 talking about the FDA denial of the Citizen</p> <p>7 Petition letter?</p> <p>8 A. Correct.</p> <p>9 Q. Sitting here today, do you know if</p> <p>10 you had it when you prepared your report?</p> <p>11 A. Honestly, I don't -- I don't recall,</p> <p>12 but the problem is, is that was not a scientific</p> <p>13 process. It was merely stating certain -- certain</p> <p>14 -- making certain statements that were not</p> <p>15 referenced or was not peer-reviewed or I had no</p> <p>16 idea how that response was determined, and all --</p> <p>17 everything that I have reviewed in here has some</p> <p>18 scientific basis behind it.</p> <p>19 So even if I had it, I'm not sure I</p> <p>20 would have included it as evidence one way or</p> <p>21 another. Because in the report, in the response,</p> <p>22 they say this has not been found, or this has not</p> <p>23 been found, or this is the case of something; but</p> <p>24 there is no evidence behind those statements.</p>
<p style="text-align: right;">Page 243</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. My question is: Do you do any</p> <p>3 analysis, that is, a written analysis in your</p> <p>4 report yourself of any FDA findings as relates to</p> <p>5 talc and ovarian cancer?</p> <p>6 MR. TISI: Okay. That's a</p> <p>7 different question. Referring to it as</p> <p>8 it's referred in Footnote B, but his --</p> <p>9 his analysis is a different question than</p> <p>10 you asked.</p> <p>11 THE WITNESS: Yeah. No, I did</p> <p>12 not. I did not do an analysis, but I did</p> <p>13 see the FDA response to a citizens</p> <p>14 committee that was made available to me.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. So was it your methodology to refer</p> <p>17 to Health Canada and IARC but not to FDA as it</p> <p>18 relates to talc and ovarian cancer?</p> <p>19 MR. TISI: Objection.</p> <p>20 Misstates.</p> <p>21 THE WITNESS: No, it was not</p> <p>22 my intent.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Why did you not refer to what FDA</p>	<p style="text-align: right;">Page 245</p> <p>1 So I'm not sure it would have met</p> <p>2 the inclusion criteria for the work -- the work</p> <p>3 that I evaluated.</p> <p>4 Q. For purposes of your methodology,</p> <p>5 what was the inclusion criteria for you to comment</p> <p>6 on something in your report?</p> <p>7 A. Scientifically reviewed evidence in</p> <p>8 the scientific literature or -- or the Health</p> <p>9 Canada report which I included because that had</p> <p>10 been peer-reviewed by externally. And things such</p> <p>11 as the IARC work that had been done.</p> <p>12 MR. HEGARTY: Let's look at a</p> <p>13 couple of things that FDA has said with</p> <p>14 regard to talc and ovarian cancer, one of</p> <p>15 which you already mentioned, and I'll</p> <p>16 mark that next.</p> <p>17 But first I wanted to mark as</p> <p>18 Exhibit 15 a printout from FDA's website</p> <p>19 as it relates to talc and ovarian cancer.</p> <p>20 (Document marked for</p> <p>21 identification as Harlow Exhibit 15.)</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. And, first of all, I'll just ask</p> <p>24 you: Have you ever looked on FDA's website and</p>

<p style="text-align: right;">Page 246</p> <p>1 determined what FDA says about talc and ovarian 2 cancer? 3 A. I haven't. 4 MR. TISI: I'm sorry. What 5 did you say this is? What are we up to? 6 MR. HEGARTY: We're at 15. 7 BY MR. HEGARTY: 8 Q. Please turn over to the next page of 9 this document. 10 Do you see the second paragraph 11 beginning "Published scientific literature"? 12 A. I'm sorry. On page 2? Yes, 13 "Published scientific literature." Yes. 14 Q. This printout from FDA's website of 15 April 3, 2024 says: 16 "Published scientific literature 17 going back to the 1960s has suggested a possible 18 association between the use of powders containing 19 talc in the genital area and the incidence of 20 ovarian cancer. However, these studies have not 21 conclusively demonstrated such a link, or if such 22 a link existed, what risk factors might be 23 involved." 24 Did I read that correctly?</p>	<p style="text-align: right;">Page 248</p> <p>1 reviewing scientific literature and why. Now I'll 2 add to my question. 3 Is that not worth referencing in 4 your report? 5 A. I have no -- there's no evidence as 6 to how are they made that evaluation. So I -- no. 7 My report was based on the 8 scientific literature, not what somebody says 9 about the scientific literature. 10 Q. You do make reference in your report 11 to review articles, though, correct? 12 A. But those are -- yes. Well, yes, 13 review articles, but those review articles are 14 peer-reviewed in the scientific literature. 15 MR. HEGARTY: Let me show 16 you -- 17 THE WITNESS: Are we done 18 with this? 19 MR. HEGARTY: We're done with 20 that document. 21 THE WITNESS: Okay. 22 MR. HEGARTY: Let me show you 23 next the FDA rejection letter of the 24 Citizen Petitions that we talked about</p>
<p style="text-align: right;">Page 247</p> <p>1 A. That's what's written, yes. 2 Q. That is a statement that does make 3 reference to FDA reviewing the scientific 4 literature, correct? 5 A. I have no idea what they base that 6 statement on. 7 MR. TISI: Can we take -- I've 8 got to make sure -- 9 MR. HEGARTY: I'm sorry? You 10 want to go off the record? 11 MR. TISI: Yeah, I've got 12 to -- 13 MR. HEGARTY: Let's go off the 14 record. 15 (Recess: 2:13 p.m. - 16 2:14 p.m.) 17 MR. HEGARTY: Let's go back on 18 the record. 19 BY MR. HEGARTY: 20 Q. We left off by talking about Exhibit 21 Number 15. You can put that exhibit -- first of 22 all, did you finish your answer to my question? 23 My question was as it relates to 24 what FDA said in that it refers specifically to</p>	<p style="text-align: right;">Page 249</p> <p>1 just a moment ago. 2 THE WITNESS: Yeah. 3 MR. HEGARTY: I marked it as 4 Exhibit 16. 5 (Document marked for 6 identification as Harlow Exhibit 16.) 7 THE WITNESS: Right. 8 MR. TISI: I'm not sure I've 9 seen this before. 10 BY MR. HEGARTY: 11 Q. Have you read before right now, 12 Doctor, Exhibit 16? 13 A. I have. 14 Q. And now looking at it, do you 15 remember when you first read Exhibit 16 in 16 relation to today? 17 A. I did not -- I do not believe I 18 looked -- I used this. I'm not sure if I had this 19 or referred to it in generating my report. 20 Q. You mentioned a moment ago that you 21 were aware that this was a letter issued in 22 response to a Citizen Petition. 23 A. I believe that's what it was. 24 Q. And as you can see in the first</p>

<p style="text-align: right;">Page 250</p> <p>1 paragraph, it actually refers to two Citizen 2 Petitions. 3 A. Okay. 4 Q. Do you see that? 5 A. Yes. 6 Q. Those Citizen Petitions were seeking 7 warnings with regard to talcum powder use and 8 ovarian cancer, correct? 9 MR. TISI: Objection. 10 Mischaracterizes. Seeking to make FDA 11 require a warning, which is different. 12 BY MR. HEGARTY: 13 Q. You can answer. 14 A. Well, this is what it specifically 15 says, for the FDA to require a cancer warning on 16 cosmetic talc products. 17 Q. Looking at the first page of 18 Exhibit 16, the third paragraph, FDA says in this 19 letter: 20 "After careful review" -- 21 A. This is right here? This paragraph? 22 Q. Yes, right here. 23 A. Got it. 24 Q. "After careful review and</p>	<p style="text-align: right;">Page 252</p> <p>1 Number 16? 2 A. From Mr. Tisi. 3 Q. Were you aware back in 2014 that FDA 4 had issued this letter? 5 A. No. 6 Q. Prior to your understanding -- let 7 me start -- ask a different way. 8 Were you aware of this letter prior 9 to being contacted by plaintiffs' counsel about 10 serving as an expert witness in this litigation? 11 A. I was not aware. 12 Q. Please turn over in Exhibit 16 to 13 page 4. Actually, it starts at page 3 and then 14 carries over to page 4. 15 A. Uh-huh. 16 Q. Do you see on those two pages where 17 FDA is describing the findings of the NTP animal 18 study that was in 1993? 19 A. Uh-huh. 20 Q. Yes, Doctor? 21 A. Yes. Yes. 22 Q. Have you read the 1993 NTP animal 23 study? 24 A. I have not.</p>
<p style="text-align: right;">Page 251</p> <p>1 consideration of the information submitted in your 2 Petitions, the comments received in response to 3 the Petitions, and review of additional scientific 4 information, this letter is to advise you that FDA 5 is denying your Petitions. FDA did not find that 6 the data submitted presented conclusive evidence 7 of a causal association between talc use in the 8 perineal area and ovarian cancer." 9 First of all, did I read that 10 correctly? 11 A. That is what it is said. 12 Q. Did you review the Citizen Petitions 13 themselves and see what they provided to FDA in 14 support of those petitions? 15 A. I did not. 16 Q. Do you understand, sitting here 17 today, that those are available and you can 18 determine what they provided to FDA? 19 A. I didn't know that they were 20 available. 21 Q. Please turn over next -- first of 22 all, before we go there. 23 How did you obtain for purposes of 24 your review the letter we're looking at, Exhibit</p>	<p style="text-align: right;">Page 253</p> <p>1 Q. Do you see where, after talking 2 about that study, on page 4 FDA says that: 3 "In light of these shortcomings, a 4 panel of experts at the 1994 IS RTP/FDA workshop 5 declared that the 1993 NTP study had no relevance 6 to human risk." 7 Do you see where I'm reading? 8 A. I do. 9 Q. Do you recall from your 10 participation in that 1994 IS RTP FDA workshop what 11 was said about the 1993 NTP study? 12 A. I don't recall, but I would have to 13 look at the minutes of the excerpt from the -- 14 from the meeting itself to see specifically what 15 was stated. 16 Q. Looking at the next paragraph, the 17 letter says: 18 "In addition, we reviewed relevant 19 toxicity literature (consisting of 15 articles 20 from 1980 to 2008), not cited in your Petitions, 21 to determine if there was additional support at 22 this point in time to for your suggested warning 23 label." 24 Does this statement from FDA of</p>



<p style="text-align: right;">Page 254</p> <p>1 their reviewing 15 articles from 1980 to 2008 not  2 satisfy your criteria for including a reference to  3 this letter in your report?  4 A. Well, I don't know. They basically  5 said, we reviewed 15 articles that were not cited  6 in the committee's petition "to determine if there  7 was additional support at this time to for your  8 suggested" scientific literature studies of acute  9 exposure effects. "FDA did not find enough  10 additional support at this point in time for your  11 suggested warning label."  12 I don't know how they made that  13 decision that there was not -- not enough evidence  14 to come to this conclusion because I don't know  15 what the 15 articles are, and they're not cited in  16 this report.  17 So I would love to be able to look  18 at those and to be able to determine whether they  19 made a decision that was based on -- on reliable  20 and scientifically valid evidence in those 15  21 articles.  22 Q. For purposes of your report, did you  23 do a comprehensive review of the toxicity  24 literature with regard to talcum powder exposure?</p>	<p style="text-align: right;">Page 256</p> <p>1 this section before today?  2 A. I have.  3 Q. This section begins:  4 "Your third major point is that  5 epidemiological studies confirm the causal  6 relation between genital application of talc and  7 ovarian cancer, and the protective effect of tubal  8 ligation or hysterectomy, preventing the  9 translocation of talc to the ovary."  10 Did I read that correctly?  11 A. You did.  12 Q. The letter goes on to say:  13 "After consideration of the  14 scientific literature submitted in support of both  15 Citizen Petitions" --  16 MR. TISI: You know, honestly,  17 you're going really fast. Can you just  18 slow down? Read it.  19 And he's actually in the  20 process of reading while you're asking a  21 question. Read what you want to read and  22 then allow him to ask the question, but  23 don't just speed read to him and ask him  24 if he agrees with it.</p>
<p style="text-align: right;">Page 255</p> <p>1 A. I didn't need to do that in order to  2 be able to assess biological plausibility.  3 Q. So you did not do that?  4 A. Correct.  5 Q. Look under the section "Epidemiology  6 and Etiology Findings."  7 MR. TISI: If you need to read  8 it, just take the time.  9 BY MR. HEGARTY:  10 Q. The first paragraph notes --  11 MR. TISI: Just a second.  12 MR. HEGARTY: Well, I'm  13 reading it for him.  14 MR. TISI: Well, no. You're  15 very selectively reading. You're  16 particularly good at it. If he needs to  17 read it, he needs to read it.  18 MR. HEGARTY: I'm not holding  19 him back.  20 MR. TISI: Okay. Well, I am  21 not either. I'm encouraging if he wants  22 to do it, to do it.  23 BY MR. HEGARTY:  24 Q. First of all, Doctor, had you read</p>	<p style="text-align: right;">Page 257</p> <p>1 BY MR. HEGARTY:  2 Q. Doctor, was I reading too fast for  3 you?  4 A. You can read at whatever speed, and  5 I will take as much time as I need to be able to  6 make sure that I digest the information.  7 MR. TISI: And he's reading.  8 I'm watching him.  9 BY MR. HEGARTY:  10 Q. And you will tell me if you need  11 more time?  12 MR. TISI: And the record will  13 reflect he's reading as you're quoting to  14 him. He's got the paper in front of him  15 as he's reading the document. So let him  16 read it or quote to him, but don't do it  17 at the same time, please.  18 BY MR. HEGARTY:  19 Q. FDA on this page we're looking at,  20 page 4 --  21 MR. TISI: You're still doing  22 it. Objection.  23 MR. HEGARTY: Fine. He'll  24 tell me if he needs more time.</p>



<p style="text-align: right;">Page 258</p> <p>1 MR. TISI: No.</p> <p>2 Are you reading the document,</p> <p>3 sir?</p> <p>4 THE WITNESS: I'm waiting.</p> <p>5 I'm waiting to see what the question is.</p> <p>6 MR. TISI: Okay.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Look at paragraph 2 on page 4. FDA</p> <p>9 writes:</p> <p>10 "Several of the studies acknowledge</p> <p>11 biases in the study design and no single study has</p> <p>12 considered all the factors that potentially</p> <p>13 contribute to ovarian cancer, including selection</p> <p>14 bias and/or uncontrolled confounding that result</p> <p>15 in spurious positive association between talc use</p> <p>16 and ovarian cancer risk."</p> <p>17 Did I read that correctly?</p> <p>18 A. You read that correctly.</p> <p>19 Q. Do you agree that several studies</p> <p>20 acknowledge the biases that are commented in that</p> <p>21 paragraph?</p> <p>22 A. I have no idea of what studies they</p> <p>23 are referring to, so I can't comment on that. If</p> <p>24 they had cited what those studies were, then I</p>	<p style="text-align: right;">Page 260</p> <p>1 scientifically valid studies did show a dose</p> <p>2 response.</p> <p>3 And just if I may?</p> <p>4 Q. And -- I'm sorry.</p> <p>5 A. With respect to lower confidence</p> <p>6 intervals of 1.0, that does not mean that the risk</p> <p>7 estimate is going to be 1.0. It just means 95</p> <p>8 percent of the time it's going to be somewhere</p> <p>9 between 1.0 and something greater, and so there is</p> <p>10 no reason to make the assumption that the</p> <p>11 association is null.</p> <p>12 Q. The next paragraph, paragraph 4,</p> <p>13 says:</p> <p>14 "A cogent biologic mechanism --</p> <p>15 biological mechanism by which talc might lead to</p> <p>16 ovarian cancer is lacking."</p> <p>17 Do you agree that that was an</p> <p>18 accurate statement as of 2014?</p> <p>19 A. No, I do not.</p> <p>20 Q. Please turn over to the next page,</p> <p>21 page 6.</p> <p>22 A. Oh, not page 5?</p> <p>23 Q. I'm sorry. Page 5. Paragraph 6</p> <p>24 starts out by referring to the IARC finding.</p>
<p style="text-align: right;">Page 259</p> <p>1 would be able to comment on it.</p> <p>2 Q. The next paragraph says:</p> <p>3 "Results of case-control studies do</p> <p>4 not demonstrate a consistent positive association</p> <p>5 across studies."</p> <p>6 Do you agree with that statement?</p> <p>7 A. No, I do not.</p> <p>8 Q. The next statement says:</p> <p>9 "Some studies have found small</p> <p>10 positive associations between talc and ovarian</p> <p>11 cancer but the lower confidence limits are often</p> <p>12 close to 1.0."</p> <p>13 First, do you agree with that part</p> <p>14 of that sentence?</p> <p>15 A. That the lower confidence limits are</p> <p>16 often close to 1.0? Yes.</p> <p>17 Q. The next part of that paragraph 3</p> <p>18 says "and dose-response evidence is lacking."</p> <p>19 Do you agree that as of 2014,</p> <p>20 dose-response evidence was lacking?</p> <p>21 A. No, I do not agree with that.</p> <p>22 We showed dose response in 1992.</p> <p>23 They showed dose response in 1999. So I know for</p> <p>24 sure there some of the biggest and I think most</p>	<p style="text-align: right;">Page 261</p> <p>1 A. Yeah.</p> <p>2 Q. Do you see that?</p> <p>3 A. I do.</p> <p>4 Q. The letter then goes on to say:</p> <p>5 "But the results of the Nurses'</p> <p>6 Health Study, a large prospective cohort study,</p> <p>7 revealed no overall association with ever talc use</p> <p>8 and epithelial ovarian cancer."</p> <p>9 That's a correct characterization of</p> <p>10 the Gertig study, correct?</p> <p>11 A. I think -- I think it is a</p> <p>12 selected -- a selected component from the study</p> <p>13 that misleads the public as to what the</p> <p>14 association truly was across different --</p> <p>15 different variations of exposure assessment.</p> <p>16 Q. With regard to this letter, do you</p> <p>17 have any experience with FDA response -- FDA's</p> <p>18 responses to Citizen Petitions?</p> <p>19 A. No, I have no idea.</p> <p>20 Q. Have you ever been involved in an</p> <p>21 FDA review of a Citizen Petition?</p> <p>22 A. I have not.</p> <p>23 Q. Have you ever discussed with anyone</p> <p>24 at FDA or otherwise how it handles Citizen</p>

<p style="text-align: right;">Page 262</p> <p>1 Petitions?</p> <p>2 A. I have not.</p> <p>3 Q. This letter was authored by Steve</p> <p>4 Musser.</p> <p>5 Do you know Steve Musser?</p> <p>6 A. I do not.</p> <p>7 Q. Is it your opinion that the doctors</p> <p>8 and scientists at FDA involved in responding to</p> <p>9 the Citizen Petition were not qualified to assess</p> <p>10 the safety data?</p> <p>11 A. I can't speak to whether they were</p> <p>12 qualified or not. I just believe that what they</p> <p>13 put forward here is -- is inaccurate.</p> <p>14 Q. Is it your belief that the -- that</p> <p>15 those involved in putting together this FDA</p> <p>16 response did not do a proper job?</p> <p>17 A. Yes.</p> <p>18 Q. Is it your contention that FDA</p> <p>19 failed to do its job with regard to the safety of</p> <p>20 talc?</p> <p>21 MR. TISI: Objection. It's</p> <p>22 not his medical --</p> <p>23 THE WITNESS: I can't -- I</p> <p>24 can't speak --</p>	<p style="text-align: right;">Page 264</p> <p>1 know, but they specifically say that "the</p> <p>2 potential for particulates to migrate</p> <p>3 from the perineum and vagina to the</p> <p>4 peritoneal cavity is indisputable."</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. What is -- what does it mean to say</p> <p>7 the potential for that to happen is</p> <p>8 "indisputable"? What's your interpretation of</p> <p>9 that phrase -- of that terminology?</p> <p>10 A. That it is plausible --</p> <p>11 Q. Phraseology.</p> <p>12 A. That it is plausible that the</p> <p>13 particulates will migrate.</p> <p>14 Q. I'm finished with that document for</p> <p>15 now, Doctor.</p> <p>16 You're familiar with the NIH,</p> <p>17 correct?</p> <p>18 A. I am.</p> <p>19 Q. In fact, your report and your CV</p> <p>20 refers to work you've done through the NIH,</p> <p>21 correct?</p> <p>22 A. Yes.</p> <p>23 Q. Including you have one grant that</p> <p>24 you're working from from NIH, correct?</p>
<p style="text-align: right;">Page 263</p> <p>1 MR. TISI: Objection. Outside</p> <p>2 the scope of the report, but you may</p> <p>3 answer.</p> <p>4 THE WITNESS: I can't speak</p> <p>5 as to what their responsibility is in</p> <p>6 this situation.</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Is it your contention that FDA</p> <p>9 believes that there is a risk of ovarian cancer</p> <p>10 with talc use and has chosen to do nothing about</p> <p>11 it?</p> <p>12 A. I --</p> <p>13 MR. TISI: Objection. Calls</p> <p>14 for speculation.</p> <p>15 THE WITNESS: Yeah. Again, I</p> <p>16 cannot speculate on that.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Is it your opinion or your belief</p> <p>19 that FDA believes there is a warning that's</p> <p>20 necessary on talcum powder products for ovarian</p> <p>21 cancer, but they're just not going to require it?</p> <p>22 MR. TISI: Objection. Calls</p> <p>23 for speculation.</p> <p>24 THE WITNESS: Yeah. I don't</p>	<p style="text-align: right;">Page 265</p> <p>1 A. I have two.</p> <p>2 Q. You also have another grant pending?</p> <p>3 A. No. No. I have a grant that I'm</p> <p>4 the PI of looking at Swedish national registry</p> <p>5 data and its -- and factors that influence</p> <p>6 unexplained vulvar pain, and I'm the PI of a</p> <p>7 subcontract with the Prevention of Lower Urinary</p> <p>8 Tract Symptoms Research Consortium on women's</p> <p>9 urological health. Those are both NIH grants.</p> <p>10 Q. You have also served on NIH</p> <p>11 committees, correct?</p> <p>12 A. I have.</p> <p>13 Q. You agree with me that the NIH is</p> <p>14 the federal government's primary health agency on</p> <p>15 cancer research in the U.S., correct?</p> <p>16 A. That's correct.</p> <p>17 Q. Do you agree that the NCI is a</p> <p>18 capable and reliable resource in this country for</p> <p>19 information on cancer?</p> <p>20 MR. TISI: Objection.</p> <p>21 THE WITNESS: Yeah. I think</p> <p>22 the -- I can't speak to their decisions</p> <p>23 on what to have as outward-facing to the</p> <p>24 public.</p>

<p style="text-align: right;">Page 266</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Do you agree that NCI is a reliable</p> <p>3 resource for doctors with regard to cancer</p> <p>4 research?</p> <p>5 MR. TISI: Objection.</p> <p>6 Objection. Vague.</p> <p>7 THE WITNESS: I think -- no.</p> <p>8 MR. TISI: Depending upon the</p> <p>9 issue. Go ahead.</p> <p>10 THE WITNESS: Yeah. No, I</p> <p>11 think a reliable resource for -- for</p> <p>12 doctors and everyone should be evidence</p> <p>13 from the scientific literature. If it is</p> <p>14 accurately evaluated, then it can be a</p> <p>15 resource in the external-facing website</p> <p>16 of the NCI.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. You have served on NCI committees,</p> <p>19 correct?</p> <p>20 A. I served on the Board of Scientific</p> <p>21 Counselors. No. Board -- board of -- I think</p> <p>22 it's the Board of Scientific Counselors for the</p> <p>23 NCI which evaluates intramural research, which is</p> <p>24 research that is done by investigators at NCI that</p>	<p style="text-align: right;">Page 268</p> <p>1 Q. Sure.</p> <p>2 Is it your contention that documents</p> <p>3 put out by NCI with regard to cancer are not</p> <p>4 necessarily reliable and can be relied upon by</p> <p>5 doctors who are treating patients for cancer?</p> <p>6 A. I can't say that that's the case</p> <p>7 across the board. I think it depends on what --</p> <p>8 what they are putting out and whether what they're</p> <p>9 putting out is -- is indisputable or is accurate</p> <p>10 in terms of representing the view of the</p> <p>11 scientific community.</p> <p>12 Q. Starting on page 16 of your report,</p> <p>13 you make reference to the NCI's Physician Data</p> <p>14 Query, or PDQ, correct?</p> <p>15 A. That's correct.</p> <p>16 Hold on. Let me just. I'll pull</p> <p>17 that up.</p> <p>18 Q. And I'll --</p> <p>19 A. Oh, in my report.</p> <p>20 Q. I'm going to mark it as an exhibit.</p> <p>21 A. Okay.</p> <p>22 Q. My reference was simply to --</p> <p>23 A. Okay.</p> <p>24 Q. -- page 16 of your report.</p>
<p style="text-align: right;">Page 267</p> <p>1 work out of NCI itself.</p> <p>2 Q. Was the work you did and reported</p> <p>3 out of that committee reliable?</p> <p>4 MR. TISI: Objection.</p> <p>5 THE WITNESS: Well, that --</p> <p>6 that committee evaluates the scientific</p> <p>7 approach and scientific rigor of research</p> <p>8 that is being done by NCI internal</p> <p>9 investigators, and they publish their</p> <p>10 research in the scientific literature,</p> <p>11 just like those of us who are outside of</p> <p>12 the NCI and any other government</p> <p>13 organization.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. So is it your testimony that</p> <p>16 anything NCI puts out with regard to cancer is not</p> <p>17 necessarily a reliable authority that doctors can</p> <p>18 rely on?</p> <p>19 MR. TISI: Objection.</p> <p>20 THE WITNESS: Yeah.</p> <p>21 MR. TISI: Form.</p> <p>22 THE WITNESS: Could you</p> <p>23 repeat that question?</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 269</p> <p>1 A. Yeah. Yeah.</p> <p>2 Q. Prior to being contacted by</p> <p>3 plaintiffs' counsel about serving as an expert</p> <p>4 witness in this litigation, had you ever read an</p> <p>5 NCI PDQ on ovarian cancer?</p> <p>6 A. I had not.</p> <p>7 Q. Since being contacted by plaintiffs'</p> <p>8 counsel about serving as an expert witness in this</p> <p>9 case, have you reviewed all the NCI PDQs on</p> <p>10 ovarian cancer that NCI has put out over the</p> <p>11 years?</p> <p>12 A. I have reviewed many of them.</p> <p>13 Q. With regard to those you reviewed,</p> <p>14 did you get them from counsel for plaintiffs?</p> <p>15 A. I -- I went -- some I got from the</p> <p>16 counsel and some I went onto the PDQ site myself</p> <p>17 and pulled off.</p> <p>18 Q. Your report on page 17 refers to the</p> <p>19 2023 NCI PDQ?</p> <p>20 A. That's correct.</p> <p>21 Q. When did you first review the NCI</p> <p>22 PDQ you refer to on page 17 of your report?</p> <p>23 A. Yeah, in the process of preparing</p> <p>24 the report.</p>

<p style="text-align: right;">Page 270</p> <p>1 MR. HEGARTY: I'm going to</p> <p>2 mark as the next exhibit, which is</p> <p>3 Exhibit 17, the current version of the</p> <p>4 NCI PDQ that is on NCI's website.</p> <p>5 (Document marked for</p> <p>6 identification as Harlow Exhibit 17.)</p> <p>7 THE WITNESS: Is this 2023?</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. If you look over on page 25 of 27,</p> <p>10 at the top, do you see where this refers to the</p> <p>11 latest update as being from March 6, 2024?</p> <p>12 A. Yeah. Ah. Yes. Yes, yes, yes.</p> <p>13 Q. Have you -- have you reviewed the</p> <p>14 March 6, 2024 NCI --</p> <p>15 A. I have.</p> <p>16 Q. -- PDQ?</p> <p>17 A. I have.</p> <p>18 Q. When did you review it --</p> <p>19 A. Recently.</p> <p>20 Q. -- first time?</p> <p>21 A. Recently, but it was not available</p> <p>22 in my report.</p> <p>23 Q. Please turn over to page 25 of 27.</p> <p>24 A. That's where we were before, right?</p>	<p style="text-align: right;">Page 272</p> <p>1 A. No, I don't -- I don't dispute that</p> <p>2 that's what they are intending to do.</p> <p>3 Q. Looking at the -- well, let me</p> <p>4 before I go there.</p> <p>5 You said that that's not -- you</p> <p>6 don't dispute that that's what they intended to</p> <p>7 do.</p> <p>8 You've read this document, correct?</p> <p>9 A. Uh-huh.</p> <p>10 Q. Yes?</p> <p>11 A. Yes.</p> <p>12 Q. Did the NCI PDQ board that put this</p> <p>13 out provide "an information summary for health</p> <p>14 professionals that provides comprehensive,</p> <p>15 peer-reviewed, evidence-based information about</p> <p>16 ovarian, fallopian tube, and primary peritoneal</p> <p>17 cancers prevention"?</p> <p>18 MR. TISI: Objection. Asked</p> <p>19 and answered.</p> <p>20 THE WITNESS: It is what they</p> <p>21 intended to do, and that's -- that's the</p> <p>22 answer.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Do you agree that they did do that,</p>
<p style="text-align: right;">Page 271</p> <p>1 Q. That's right.</p> <p>2 A. "About This PDQ Summary"?</p> <p>3 Q. Yes. Under the section "Purpose of</p> <p>4 This Summary."</p> <p>5 Do you see where I'm pointing to?</p> <p>6 A. Yes, uh-huh.</p> <p>7 Q. It states that:</p> <p>8 "This PDQ cancer information summary</p> <p>9 for health professionals provides comprehensive</p> <p>10 peer-reviewed, evidence-based information about</p> <p>11 ovarian fallopian tube, and primary peritoneal</p> <p>12 cancers prevention."</p> <p>13 Do you dispute that that's what this</p> <p>14 NCI PDQ does?</p> <p>15 A. That's what they indicate it does.</p> <p>16 Q. My question, though, is: Do you</p> <p>17 dispute that that's what this NCI PDQ does?</p> <p>18 MR. TISI: Objection. Asked</p> <p>19 and answered.</p> <p>20 THE WITNESS: That's what</p> <p>21 they specifically say it does.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Do you dispute that that's what this</p> <p>24 NCI PDQ does?</p>	<p style="text-align: right;">Page 273</p> <p>1 not that they intended to do it?</p> <p>2 A. No, I agree that they did it.</p> <p>3 Q. Okay. Under the section "Reviewers</p> <p>4 and Updates," do you see where --</p> <p>5 A. Where is that?</p> <p>6 Q. It's in the same page just below</p> <p>7 where we were reading.</p> <p>8 A. Same page?</p> <p>9 Q. Still page 25 of 27.</p> <p>10 A. Oh. I'm sorry. 25 of 27. No, I</p> <p>11 was -- oh, okay. I'm sorry. Where on 25 again?</p> <p>12 Q. Under the section "Reviewers and</p> <p>13 Updates."</p> <p>14 MR. TISI: Right here.</p> <p>15 THE WITNESS: Got it.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. The second paragraph says:</p> <p>18 "Board members review recently</p> <p>19 published articles each month to determine whether</p> <p>20 an article should: be discussed at a meeting, be</p> <p>21 cited with text, or" -- turn the page.</p> <p>22 A. Uh-huh.</p> <p>23 Q. "Replace or update an existing</p> <p>24 article that is already cited."</p>

<p style="text-align: right;">Page 274</p> <p>1 Did I read that correctly?</p> <p>2 MR. TISI: He just read the</p> <p>3 second paragraph. Please read the whole</p> <p>4 thing, sir.</p> <p>5 MR. HEGARTY: Chris, can you</p> <p>6 wait until you ask your questions?</p> <p>7 MR. TISI: No. Honestly,</p> <p>8 you --</p> <p>9 MR. HEGARTY: That rule does</p> <p>10 not apply at depositions.</p> <p>11 MR. TISI: All right.</p> <p>12 MR. HEGARTY: You know that.</p> <p>13 MR. TISI: You know, you</p> <p>14 know -- you know what you are doing. You</p> <p>15 are cherry-picking. You are</p> <p>16 cherry-picking sentences out of context,</p> <p>17 and I want him to have the opportunity to</p> <p>18 read the documents that you put in front</p> <p>19 of him.</p> <p>20 MR. HEGARTY: You will have</p> <p>21 your turn at the end of my examination to</p> <p>22 ask him that.</p> <p>23 MR. TISI: I understand, but,</p> <p>24 you know, honestly, it's unfair to ask a</p>	<p style="text-align: right;">Page 276</p> <p>1 answer the question you just gave him?</p> <p>2 (Document marked for</p> <p>3 identification as Harlow Exhibit 18.)</p> <p>4 MR. TISI: Go ahead. Next</p> <p>5 one.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. I marked this document as</p> <p>8 Exhibit 19.</p> <p>9 A. I believe it says 18.</p> <p>10 Q. I'm sorry. Thank you for correcting</p> <p>11 me. Exhibit 18. I don't want to mess up the</p> <p>12 exhibits.</p> <p>13 A. Uh-huh.</p> <p>14 Q. Have you reviewed the list of PDQ</p> <p>15 Screening and Prevention Editorial Board Members</p> <p>16 Report right now?</p> <p>17 A. I have, actually.</p> <p>18 Q. Do you know any of the board</p> <p>19 members?</p> <p>20 A. I do not.</p> <p>21 Q. There is a board member from</p> <p>22 University of Washington.</p> <p>23 Do you know her?</p> <p>24 A. I don't.</p>
<p style="text-align: right;">Page 275</p> <p>1 witness without giving the opportunity to</p> <p>2 read. You're not asking him: Do you</p> <p>3 need to read this? Do you need to read</p> <p>4 the entire sentence?</p> <p>5 You're just reading sentences</p> <p>6 and ask him: Did I read this correctly?</p> <p>7 MR. HEGARTY: Please limit</p> <p>8 your objections --</p> <p>9 MR. TISI: No, I'm not going</p> <p>10 to.</p> <p>11 MR. HEGARTY: -- to what the</p> <p>12 court has asked us all to do, which is to</p> <p>13 form of the question.</p> <p>14 MR. TISI: I have been doing.</p> <p>15 I have almost made no objections.</p> <p>16 I do object to you taking</p> <p>17 documents, reading sentences out of</p> <p>18 context and ask if you read them</p> <p>19 correctly. Objection to form.</p> <p>20 MR. HEGARTY: Doctor, I'm</p> <p>21 going to mark next as Exhibit 18 the PDQ</p> <p>22 Screening and Prevention Editorial Board.</p> <p>23 MR. TISI: So there's no</p> <p>24 question? You're not going to let him</p>	<p style="text-align: right;">Page 277</p> <p>1 Q. There's also a board member from</p> <p>2 Harvard Medical School, Lydia Pace.</p> <p>3 Do you know her?</p> <p>4 A. I don't.</p> <p>5 Q. Do you contend that the members of</p> <p>6 the NCI PDQ board that are responsible for the NCI</p> <p>7 PDQ on ovarian cancer are not experts in their</p> <p>8 fields?</p> <p>9 MR. TISI: Objection.</p> <p>10 THE WITNESS: I don't know</p> <p>11 what their fields are. I don't know</p> <p>12 whether they are experts on evaluating</p> <p>13 talc and ovarian cancer risk.</p> <p>14 BY MR. HEGARTY:</p> <p>15 Q. Do you contend that the members of</p> <p>16 the NCI PDQ Board that we're looking at in</p> <p>17 Exhibit 18 did not review the pertinent literature</p> <p>18 on talcum powder and ovarian cancer in preparing</p> <p>19 Exhibit Number 17?</p> <p>20 A. No, I don't dispute that they didn't</p> <p>21 review the literature.</p> <p>22 Q. Do you contend that they do not</p> <p>23 stand behind the statements in the PDQ about talc</p> <p>24 and ovarian cancer that we marked as Exhibit 17?</p>



<p style="text-align: right;">Page 278</p> <p>1 A. I would assume that they do.</p> <p>2 Q. Do you contend that the statements</p> <p>3 that they make in the NCI PDQ on ovarian cancer</p> <p>4 and talc are false?</p> <p>5 MR. TISI: Take a look at it</p> <p>6 before.</p> <p>7 THE WITNESS: What particular</p> <p>8 statements are we referring to?</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. In Exhibit 17, the statements on</p> <p>11 talc and ovarian cancer over on page 21 of 27</p> <p>12 carrying over to page 22 of 27.</p> <p>13 A. Right. There we go.</p> <p>14 Q. First of all, before I ask, I'll go</p> <p>15 back to that question.</p> <p>16 You have read before today the</p> <p>17 section on "Perineal Talc Exposure" on pages 21</p> <p>18 and 22?</p> <p>19 A. Yes.</p> <p>20 Q. You're familiar with what that says,</p> <p>21 correct?</p> <p>22 A. I am.</p> <p>23 Q. Going back to my question: Do you</p> <p>24 contend that the statements in the section on</p>	<p style="text-align: right;">Page 280</p> <p>1 fact that meta-analyses did not show any kind of a</p> <p>2 dose-response relationship, but the overall</p> <p>3 association cited I agree with.</p> <p>4 Oh, and also in their citation of</p> <p>5 the -- of the pooled analysis from the Ovarian</p> <p>6 Cancer Association Consortium, I agree with their</p> <p>7 citation of what the overall association. But</p> <p>8 their -- their -- their contention that lifetime</p> <p>9 numbers of applications was not -- was not</p> <p>10 statistically significant, making an assumption</p> <p>11 that there was no increase in risk with increasing</p> <p>12 numbers of exposure, was simply based on</p> <p>13 statistical significance.</p> <p>14 Whereas, as I recall when going back</p> <p>15 and looking at that, and you look at the lower and</p> <p>16 upper 95 percent confidence bounds, you see a</p> <p>17 shifting of increased risk over increasing</p> <p>18 exposure.</p> <p>19 So the way in which they</p> <p>20 characterize that I felt was not accurate.</p> <p>21 They cite -- they cite that the</p> <p>22 subset analysis of the prospective study -- I</p> <p>23 believe that was by Woolen; is that correct? Is</p> <p>24 that the citation?</p>
<p style="text-align: right;">Page 279</p> <p>1 "Perineal Talc Exposure" are false?</p> <p>2 MR. TISI: Objection. Take a</p> <p>3 look if you need to.</p> <p>4 THE WITNESS: (Reviews</p> <p>5 document.)</p> <p>6 There are some statements here</p> <p>7 that I believe are false.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. Which statements do you believe are</p> <p>10 false?</p> <p>11 A. The first sentence.</p> <p>12 Q. Any other statements?</p> <p>13 A. "Results from case" --</p> <p>14 Q. I'm sorry. Go ahead.</p> <p>15 A. "Results from case-control and</p> <p>16 cohort studies are inconsistent, so the data are</p> <p>17 inadequate to support an association between</p> <p>18 perineal talc exposure and an increased risk of</p> <p>19 ovarian cancer."</p> <p>20 Q. What other statements do you contend</p> <p>21 in that section are false?</p> <p>22 A. Hang on a second. Right.</p> <p>23 I take issue with the next sentence</p> <p>24 that cited the study by Huncharek as -- as the</p>	<p style="text-align: right;">Page 281</p> <p>1 Q. Yes.</p> <p>2 A. Yeah. They -- they -- they said --</p> <p>3 yeah, they -- yeah, they -- they were -- let's</p> <p>4 see.</p> <p>5 The subset analysis of the</p> <p>6 prospective study was essentially made by the</p> <p>7 original report.</p> <p>8 Right. First of all, I think they</p> <p>9 made an incorrect -- they made an incorrect</p> <p>10 citation in this.</p> <p>11 But in any case, I believe that they</p> <p>12 were stating something about the approach of</p> <p>13 excluding two of the three cohort studies was sort</p> <p>14 of cherry-picking, and I believe that it was not,</p> <p>15 and that the other two cohort studies are -- are</p> <p>16 very much flawed in terms of selection bias and</p> <p>17 exposure assessment.</p> <p>18 (Reviews document.)</p> <p>19 Again, I feel that the first</p> <p>20 sentence of the next paragraph where they chose to</p> <p>21 only discuss the overall association of 1.09 and</p> <p>22 not the fact that there was stronger associations</p> <p>23 observed when more appropriately assessing the</p> <p>24 exposure that was -- was left out.</p>

<p style="text-align: right;">Page 282</p> <p>1 And I think any reference to the</p> <p>2 Women's Health Initiative is flawed because they</p> <p>3 didn't start recruiting women until after the age</p> <p>4 of 50, when many women who would have already been</p> <p>5 diagnosed with ovarian cancer could not have been</p> <p>6 included, and so I find that to be a poor example</p> <p>7 of a cohort study to be used to assess this</p> <p>8 association.</p> <p>9 I think that's plenty.</p> <p>10 Q. You make the statement in your</p> <p>11 expert report at page 17 --</p> <p>12 A. Yes.</p> <p>13 Q. -- that the -- that with regard to</p> <p>14 the comment on the Woolen study that they</p> <p>15 "incorrectly cited in the PDQ report as O'Brien et</p> <p>16 al."</p> <p>17 Do you see where I'm referring you</p> <p>18 to?</p> <p>19 A. Yes, I do.</p> <p>20 Q. What do you mean when you say</p> <p>21 "incorrectly cited in the PDQ report as O'Brien et</p> <p>22 al."?</p> <p>23 A. I believe they -- they made an error</p> <p>24 in which study they were citing. So.</p>	<p style="text-align: right;">Page 284</p> <p>1 incorrect?</p> <p>2 A. Hold on a second. I might have made</p> <p>3 a mistake, which can happen.</p> <p>4 (Reviews document.)</p> <p>5 "Was inconsistent with the main</p> <p>6 findings." The meaning of the statement is</p> <p>7 unclear. The PDQ goes on to cite the Gertig</p> <p>8 analysis.</p> <p>9 That might have been an error in the</p> <p>10 citation there.</p> <p>11 Q. You've read the Woolen paper,</p> <p>12 correct?</p> <p>13 A. I have.</p> <p>14 Q. And you saw where they used a subset</p> <p>15 of data from the Nurses' Health Study 1, correct?</p> <p>16 A. Yes.</p> <p>17 Q. That subset of data was unpublished</p> <p>18 data, correct?</p> <p>19 A. I believe they actually got it from</p> <p>20 the Nurses' Health Study. That's my -- that's my</p> <p>21 understanding.</p> <p>22 MR. HEGARTY: I'll mark so you</p> <p>23 can look at it --</p> <p>24 THE WITNESS: Yeah.</p>
<p style="text-align: right;">Page 283</p> <p>1 Q. Why do you believe they made an</p> <p>2 error?</p> <p>3 A. Because I thought that they cited</p> <p>4 the wrong -- they made the wrong citation.</p> <p>5 So what's inconsistent with the</p> <p>6 meaning of this statement is unclear, but the PDQ</p> <p>7 goes on to cite the Gertig analysis.</p> <p>8 So in -- let's see. When they talk</p> <p>9 about the Gertig analysis, which is the 1.09,</p> <p>10 reference 13 -- no, that wasn't it. There was</p> <p>11 another location I thought.</p> <p>12 Q. And the reason I ask you --</p> <p>13 A. Yeah.</p> <p>14 Q. -- is because at the end of that</p> <p>15 sentence that you're referring to, it says:</p> <p>16 "The subset analysis" -- that same.</p> <p>17 A. Oh.</p> <p>18 Q. "The subset analysis of the</p> <p>19 prospective study was inconsistent with the main</p> <p>20 findings of the original report" refers to the</p> <p>21 O'Brien study, correct?</p> <p>22 A. Yeah.</p> <p>23 Q. So do you still say that their</p> <p>24 reference at the end of that sentence was</p>	<p style="text-align: right;">Page 285</p> <p>1 MR. HEGARTY: -- as Exhibit</p> <p>2 Number 19 the Woolen paper.</p> <p>3 (Document marked for</p> <p>4 identification as Harlow Exhibit 19.)</p> <p>5 THE WITNESS: Yeah.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. This is a paper you've read,</p> <p>8 correct?</p> <p>9 A. Yes.</p> <p>10 Q. If you look over on the second page,</p> <p>11 in the upper right-hand corner, it describes that</p> <p>12 the -- it describes the data that they got from</p> <p>13 the Nurses' Health Study, correct?</p> <p>14 In particular, if you look at the</p> <p>15 very last couple of sentences, it says:</p> <p>16 "The data from NHS 1" --</p> <p>17 MS. PARFITT: Mark, I'm sorry.</p> <p>18 Where are you?</p> <p>19 MR. HEGARTY: I'm on page --</p> <p>20 THE WITNESS: 2527.</p> <p>21 MR. HEGARTY: -- 2527 in the</p> <p>22 upper right-hand corner.</p> <p>23 MS. PARFITT: Thank you.</p> <p>24 BY MR. HEGARTY:</p>

<p style="text-align: right;">Page 286</p> <p>1 Q. It says:</p> <p>2 "The data from NHS 1 were provided</p> <p>3 and described in the Supplemental Table 1 and are</p> <p>4 included in the systematic review. The data from</p> <p>5 the SIS study were not provided to us due to the</p> <p>6 small sample size of exposed individuals in the</p> <p>7 highest exposure category."</p> <p>8 What that section is saying is that</p> <p>9 they got the data from the NHS 1 study, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. And do you understand that that was</p> <p>12 unpublished data?</p> <p>13 A. I don't know whether it was</p> <p>14 unpublished. They just got the actual data</p> <p>15 itself. It may have been part of the Gertig</p> <p>16 analysis.</p> <p>17 Q. Please look over to page 2569 -- I'm</p> <p>18 sorry -- 2529.</p> <p>19 At the very bottom where the</p> <p>20 footnote is referring to, that is Footnote 5</p> <p>21 referring to O'Brien?</p> <p>22 A. Yes.</p> <p>23 Q. The NHS data.</p> <p>24 Do you see where it says:</p>	<p style="text-align: right;">Page 288</p> <p>1 me exactly where that is.</p> <p>2 BY MR. HEGARTY:</p> <p>3 Q. Sure. I'm looking now back at the</p> <p>4 NCI PDQ.</p> <p>5 A. Okay. Let me just go back to the</p> <p>6 NCI PDQ.</p> <p>7 Q. Back to the section that you called</p> <p>8 out in your report.</p> <p>9 A. Yes.</p> <p>10 Q. And do you see where in the NCI PDQ</p> <p>11 it says:</p> <p>12 "The subset analysis of the</p> <p>13 prospective study" -- that's the NHS study -- "was</p> <p>14 inconsistent with the main findings of the</p> <p>15 original report" citing to O'Brien.</p> <p>16 So what they're saying there is that</p> <p>17 the subset analysis in Woolen was inconsistent</p> <p>18 with the overall reported findings from O'Brien,</p> <p>19 correct?</p> <p>20 MR. TISI: Objection.</p> <p>21 THE WITNESS: (Reviews</p> <p>22 document.)</p> <p>23 Yes, it appears that they --</p> <p>24 that they have additional -- they had</p>
<p style="text-align: right;">Page 287</p> <p>1 "O'Brien did not publish on daily</p> <p>2 exposure for the National Health Study</p> <p>3 participants. However, these data were available</p> <p>4 and O'Brien provided these data for inclusion"?</p> <p>5 A. Yes, I see that.</p> <p>6 Q. Is that telling you that the data</p> <p>7 that's reported as to -- as to Study 11 in the</p> <p>8 table above was unpublished data?</p> <p>9 A. (Reviews document.)</p> <p>10 It may have been. I just don't</p> <p>11 know.</p> <p>12 Q. And going back to your report, what</p> <p>13 NCI is saying in this PDQ is that the findings in</p> <p>14 Woolen, which represent a subset analysis, was</p> <p>15 inconsistent with the main findings of the</p> <p>16 original report, and they refer to O'Brien.</p> <p>17 So what they're saying there is that</p> <p>18 the Woolen findings were inconsistent with the</p> <p>19 overall findings of what O'Brien reported in their</p> <p>20 2020 report.</p> <p>21 Do you see that?</p> <p>22 MR. TISI: Objection.</p> <p>23 Misstates.</p> <p>24 THE WITNESS: So show -- show</p>	<p style="text-align: right;">Page 289</p> <p>1 additional information that was not part</p> <p>2 of it. That's correct.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. So what they say or what they cite</p> <p>5 to for the statement that you called out in your</p> <p>6 report is accurate, correct?</p> <p>7 MS. PARFITT: Objection.</p> <p>8 Sorry.</p> <p>9 MR. TISI: Objection.</p> <p>10 THE WITNESS: Yeah, I may have</p> <p>11 -- I may have misinterpreted that.</p> <p>12 I was -- when I was looking at</p> <p>13 this, my concern was that people felt</p> <p>14 that the exclusion of the sisters health</p> <p>15 study -- the Sister Study and the Women's</p> <p>16 Health Initiative were a concern on the</p> <p>17 part of the PDQ, and my belief was that</p> <p>18 it was an appropriate exclusion from</p> <p>19 their analyses.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Ultimately, in the NCI PDQ, the</p> <p>22 document itself says that:</p> <p>23 "Results from case-control and</p> <p>24 cohort studies are inconsistent, so the data are</p>

<p style="text-align: right;">Page 290</p> <p>1 inadequate to support an association between  2 perineal talc exposure and an increased risk of  3 ovarian cancer."  4 That's what they say, correct?  5 A. The first sentence there, which is  6 what I disputed.  7 Q. You disagree with that?  8 A. I -- correct.  9 Q. And with regard to the Gertig study,  10 which you thought they intended to reference, that  11 study, as we looked at earlier, reported no  12 overall association between epithelial ovarian  13 cancer and ever use of talc, correct?  14 A. They reported a 1.09 relative risk  15 with a confidence interval of 0.86 to 1.37, which  16 suggests that the risk falls somewhere between  17 there.  18 Q. Going back to the Board that we  19 talked about earlier, the NCI PDQ Board.  20 A. Yes.  21 Q. Is it your contention that they  22 failed in their responsibility to doctors to put  23 out accurate statements about the risk factors for  24 ovarian cancer, in particular perineal talc</p>	<p style="text-align: right;">Page 292</p> <p>1 doctors reading this NCI PDQ should not rely on it  2 in treating their patients?  3 A. What doctors?  4 Q. Doctors treating patients for  5 ovarian cancer.  6 A. Well, if they're already treating  7 them for ovarian cancer, it doesn't -- this  8 doesn't relate to that. This doesn't provide  9 guidance on treatment approaches for it.  10 Q. Is it your opinion that the summary  11 that is in the NCI PDQ about perineal talc  12 exposure and ovarian cancer is not a reliable  13 summary?  14 A. Yes, I would agree with that.  15 Q. You can put that document aside for  16 the moment.  17 You make reference in your report --  18 MR. TISI: How long have we  19 been on the record?  20 MR. HEGARTY: You want to take  21 a break?  22 MR. TISI: I just want to take  23 every hour or so.  24 MR. HEGARTY: Sure. Let's go</p>
<p style="text-align: right;">Page 291</p> <p>1 exposure?  2 A. I --  3 MR. TISI: Objection.  4 THE WITNESS: Well, I believe  5 I went through the error -- besides the  6 issue that I may have misinterpreted,  7 there were several other statements that  8 I indicated that I felt were misleading.  9 BY MR. HEGARTY:  10 Q. My question, though, is a little bit  11 different than that.  12 Is it your contention that the PDQ  13 Board members failed in their responsibilities to  14 doctors to put out accurate statements about  15 perineal talc use and ovarian cancer?  16 A. I guess by looking at that first  17 sentence of "results from case-control and cohort  18 studies are inconsistent, so the data are  19 inadequate to support an association between  20 perineal talc exposure and an increased risk of  21 ovarian cancer" is a -- I would say, yes, they  22 failed in their duty to accurately -- accurately  23 explain the results.  24 Q. Is it your contention that the</p>	<p style="text-align: right;">Page 293</p> <p>1 off the record.  2 (Recess: 2:58 p.m. -  3 3:10 p.m.)  4 MR. HEGARTY: We are back on  5 the record.  6 BY MR. HEGARTY:  7 Q. Doctor, I want to shift gears a  8 little bit. Unless you got something else you  9 wanted to say?  10 A. No, I'll wait till later.  11 Q. Okay.  12 MR. TISI: Well, if you do  13 have something else to say, go ahead.  14 THE WITNESS: Well --  15 BY MR. HEGARTY:  16 Q. You have something you want to say  17 with regard to the subject we were talking about,  18 the NCI PDQ?  19 A. Yes. Just the fact that in this  20 sentence where it says "The subset analysis of the  21 prospective study was inconsistent with the main  22 findings of the original report," when I think  23 about the original report of the Nurses' Health  24 Study, which is what that prospective study is, I</p>

<p style="text-align: right;">Page 294</p> <p>1 was assuming they were referring to Gertig because  2 that was the original.  3 I didn't -- but, in fact, in this,  4 which is very confusing, they talk about the  5 original report as being O'Brien. But that wasn't  6 the original report. Because the sentence before  7 that was talking about Woolen.  8 So they talk about Woolen finding  9 the 1.47, but then they say "The subset analysis  10 of the prospective study," which they say was --  11 was done by -- which was -- the prospective --  12 "The subset analysis of the prospective study was  13 inconsistent with the main findings of the  14 original report."  15 Well, when you talk about the  16 original report, there's no reference to O'Brien's  17 report here. The reference should be to -- maybe  18 they didn't mean it to be original report, but  19 that's the reason why I thought it should have  20 been Gertig and not O'Brien.  21 Q. Okay.  22 A. And that was my -- that was the  23 confusion there.  24 Q. Okay. Thank you.</p>	<p style="text-align: right;">Page 296</p> <p>1 Q. Are you aware, though, that there  2 was a follow-up study --  3 MR. TISI: Do you need the  4 article?  5 THE WITNESS: No, I have it.  6 BY MR. HEGARTY:  7 Q. Are you aware that there was a  8 follow-up study done reported with the first  9 author of Gates in 2010 that had 10 more years of  10 data from the Nurses' Health Study?  11 A. Yes.  12 Q. Have you read the Gertig -- I'm  13 sorry -- the Gates 2010 study?  14 A. I believe I did.  15 MR. HEGARTY: I've marked as  16 Exhibit Number 20 that study.  17 THE WITNESS: Yeah.  18 (Document marked for  19 identification as Harlow Exhibit 20.)  20 BY MR. HEGARTY:  21 Q. Have you read Exhibit Number 10, the  22 Gates 2010 study?  23 A. Yes.  24 Q. Exhibit 20. I'm sorry.</p>
<p style="text-align: right;">Page 295</p> <p>1 You make reference in your report at  2 several places to the finding from the Gertig  3 study about the relative risk or, I should say,  4 odds ratios reported for serous cancer, correct?  5 A. Yes.  6 Q. The authors, as you know, reported  7 an odds ratio of 1.40 from that 2000 Gertig study,  8 correct?  9 A. Let me just -- just give me a moment  10 to -- to get the Gertig study open and take a  11 look.  12 Okay. So now can you repeat the  13 question?  14 Q. Sure.  15 You make reference in your report --  16 A. Oh, in my report.  17 Q. -- to the finding from Gertig of  18 1.04 odds ratio for serous adenocarcinoma.  19 A. Oh. I believe so.  20 Again, let me just go to that. That  21 was with the Nurses' Health Study.  22 1.40 they report odds ratio for  23 invasive serous ovarian cancer. Yes, that's  24 correct.</p>	<p style="text-align: right;">Page 297</p> <p>1 A. Yes, I know that I had reviewed  2 this.  3 Q. So have you read Exhibit Number 20,  4 the Gates 2010 study?  5 A. Yeah, I have it in front of me.  6 Yes.  7 Yes, I had read that.  8 Q. Please turn over to Table 4 on page  9 50 of that study.  10 Tell me when you're there.  11 A. I'm there.  12 Q. The authors reported that as to talc  13 and serous invasive ovarian cancer, the relative  14 risk they found 10 years later with 10 years  15 additional data was 1.06 with a confidence  16 interval of .84 to 1.35, correct?  17 A. That is correct, but it's only for  18 dichotomous of exposure, greater than once per  19 week or less than once per week.  20 Q. Did you do any analysis as to  21 whether that is a different result than ever  22 never?  23 A. I didn't do an analysis, no, but it  24 is a different. And what's -- what's interesting</p>



<p style="text-align: right;">Page 298</p> <p>1 about that, greater than -- let me just see. Let 2 me look. 3 "Estimates were adjusted for all 4 variables." 5 Well, I don't know whether the less 6 than once per week includes those who were 7 unexposed as well. 8 I'm just looking to see if that's 9 the case. 10 Because if it does not, if it -- if 11 it mixes together those who were unexposed with 12 those who were exposed less than once a week, then 13 it would naturally attenuate the association. 14 Q. In preparing your report, you did 15 not make reference to this finding from Gates, 16 correct? 17 A. No, I didn't. I don't believe I 18 did. 19 Q. Did you consciously make a decision 20 not to refer to this finding from the Gates 2010 21 study? 22 A. I did not consciously make that 23 decision. It's there's no new data. All it was 24 was additional -- it was additional follow-up</p>	<p style="text-align: right;">Page 300</p> <p>1 the exposures that they -- that they chose to look 2 at with regard to talcum powder use and serous 3 invasive ovarian cancer, correct? 4 A. Yes. Yes. 5 Q. That number is quite different than 6 the 1.40 number that you reference in your report 7 from Gertig 2000, correct? 8 MR. TISI: Objection. 9 THE WITNESS: Well, it's -- 10 again, it's -- it's different, but it's a 11 shifting down of the association because 12 of the mixing of the effects of exposed 13 and unexposed in the -- in the reference 14 grouping. 15 BY MR. HEGARTY: 16 Q. Have you done any analysis as to 17 what that mixing effect had on the overall number? 18 A. I don't need to do that. Because if 19 you believe that -- that -- and as it's been shown 20 in a number of studies -- that any use of talc is 21 associated with about 1.3 excess risk, if you take 22 some of those people who were exposed and put them 23 into the reference group, it's going to attenuate 24 the association.</p>
<p style="text-align: right;">Page 299</p> <p>1 period of time. 2 Q. Isn't this, though, at least some 3 data that is contrary to the 1.4 odds ratio 4 finding from the Gertig 2000 paper as it relates 5 to serous invasive tumors? 6 A. Let me look at the Gertig. 7 It's actually -- again, it's -- it's 8 quite different. Because in the Gertig paper, 9 they left those who were completely unexposed as 10 unexposed as the reference, and then they looked 11 at those who were exposed. 12 Here you have a mixing of unexposed 13 and exposed in the reference category. 14 Q. Going back to my question, though, 15 is that it is at least some data that -- (voice 16 speaking on phone) -- relates to the odds ratio or 17 point estimate for serous invasive ovarian cancer 18 and talcum powder use from that Gertig data, 19 correct? 20 A. I'm sorry. Repeat. Repeat the 21 question. 22 Q. Sure. I apologize. 23 A. No worries. 24 Q. You do agree it is data reporting on</p>	<p style="text-align: right;">Page 301</p> <p>1 Q. There are a number of studies that 2 you don't cite that found as far as for serous 3 adenocarcinoma, serous invasive adenocarcinoma, no 4 statistically significant increase in risk. Those 5 include Houghton. They include the O'Brien study. 6 Are you aware of that? 7 MR. TISI: Objection. 8 THE WITNESS: I guess I'd 9 like to look at those. I mean, the -- 10 I'd like to just take a quick look, but 11 not every study is going to show exactly 12 the same figures. 13 BY MR. HEGARTY: 14 Q. Let me ask this in a very general 15 way. 16 MR. TISI: While he's doing 17 that, I really have something. 18 MR. HEGARTY: That's fine. 19 Off the record. 20 (Recess: 3:19 p.m. - 21 3:22 p.m.) 22 MR. HEGARTY: So we are back 23 on the record. 24 BY MR. HEGARTY:</p>

<p style="text-align: right;">Page 302</p> <p>1 Q. When we interrupted -- when we broke  2 very quickly, I had a question pending. Let me  3 restate that.  4 A. Please.  5 Q. Are you aware that some studies have  6 reported odds ratios of relative risk for talcum  7 powder use and serous invasive ovarian cancer that  8 were not statistically significant?  9 A. Oh. Yes.  10 Q. Those included the WHI Houghton  11 study, correct?  12 A. Yes, but I might want to point out  13 that their association was pretty much consistent  14 with what we've seen in the other studies, being  15 1.13 as an association with a confidence interval  16 of 0.84 to 1.51 and in the -- and that's in the  17 WHI, which in and of itself I've already suggested  18 underestimates the association because of the fact  19 that they only include women 50 years of age and  20 older.  21 And then in the O'Brien study,  22 actually, if you look at the serous for frequent  23 users, it's got a confidence interval of 0.9 to  24 1.28. So, again, that's also -- that's also</p>	<p style="text-align: right;">Page 304</p> <p>1 look in my report for those particular reviews,  2 but let me just quickly do that if I may.  3 So for the Women's Health  4 Initiative, yes, I do. Multivariate adjusted  5 hazard ratio for serous ovarian tumors was 1.16  6 with a confidence interval of 0.88 to 1.53.  7 And for -- I'm sorry. What was the  8 other one?  9 Q. O'Brien 2020.  10 A. Oh, yeah.  11 And for O'Brien, I don't believe I  12 -- I don't talk about that one in my summary in  13 the report.  14 Q. Let me ask you some basic  15 information, or let me ask you about some basic  16 information.  17 A. Yeah.  18 Q. The cancer at issue, as we've been  19 talking about, is ovarian cancer, correct?  20 A. The cancer at issue is the ovarian  21 cancer, yes.  22 Q. You have not been involved in the  23 care and treatment of any patient who has had  24 ovarian cancer, correct?</p>
<p style="text-align: right;">Page 303</p> <p>1 comparable given that they're mixing in in this  2 study, the WHI and the Sister Study, which have  3 significant exposure assessment flaws.  4 Q. Both of those point estimates that  5 you cite to are not statistically significant,  6 correct?  7 A. They -- the confidence interval  8 includes 1, but it doesn't mean that it's a null  9 association.  10 Q. Where a confidence interval  11 includes 1, the result could be due to chance,  12 correct?  13 A. Well, even a confidence interval  14 that doesn't include 1 could be due to chance.  15 Q. But a confidence interval that  16 includes 1 means that the real point estimate  17 could be 1.0?  18 A. It could be 1.0, but it's not likely  19 to be skewed toward the lower end. It's likely to  20 be somewhere in the middle.  21 Q. You don't reference anywhere --  22 anywhere in your report the serous invasive  23 findings from Houghton or from O'Brien, correct?  24 A. I'd have to look in -- I'd have to</p>	<p style="text-align: right;">Page 305</p> <p>1 A. I am not a physician.  2 Q. You have no medical training in  3 gynecologic oncology, correct?  4 A. That is correct.  5 Q. You have no expertise in diagnosing  6 ovarian cancer, correct?  7 A. I am not a clinician.  8 Q. You have no expertise in diagnosing  9 mesothelioma, correct?  10 A. Correct.  11 Q. You have no expertise in analyzing a  12 patient's risk factors for ovarian cancer,  13 correct?  14 Let me ask it a different way.  15 You have never analyzed a patient's  16 risk factors for ovarian cancer outside of work  17 you've done for litigation, correct?  18 A. Correct.  19 MR. TISI: Object.  20 BY MR. HEGARTY:  21 Q. Outside of litigation, you've never  22 attempted to look at a particular patient's  23 various risk factors and identify which, if any,  24 may have contributed to the development of her</p>

<p style="text-align: right;">Page 306</p> <p>1 ovarian cancer, correct?</p> <p>2 A. I've always worked at the population</p> <p>3 level.</p> <p>4 Q. Outside of perhaps the cases you've</p> <p>5 consulted on for litigation, you never came to the</p> <p>6 opinion that talc caused any woman's ovarian</p> <p>7 cancer, correct?</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: I have not</p> <p>10 published any or made any kind of</p> <p>11 statement regarding that.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. And regardless of publishing or</p> <p>14 making any statement, you have not concluded, even</p> <p>15 where you have not shared it with anyone, that any</p> <p>16 particular patient's ovarian cancer was caused by</p> <p>17 talcum powder use, correct?</p> <p>18 A. No, because I would not have been in</p> <p>19 position to do that.</p> <p>20 Q. You also never came to the opinion</p> <p>21 that any woman's exposure to asbestos caused her</p> <p>22 ovarian cancer, correct?</p> <p>23 A. I have not been in position to do</p> <p>24 that.</p>	<p style="text-align: right;">Page 308</p> <p>1 A. That is a fair statement.</p> <p>2 Q. You're also not an expert on animal</p> <p>3 studies, true?</p> <p>4 A. That's true.</p> <p>5 Q. You're not an expert on cell</p> <p>6 studies, correct?</p> <p>7 A. That's true.</p> <p>8 Q. Do you consider yourself an expert</p> <p>9 on talc as a mineral?</p> <p>10 A. I consider myself an expert on the</p> <p>11 epidemiologic data looking at the association</p> <p>12 between talc and ovarian cancer.</p> <p>13 Q. Do you consider yourself an expert</p> <p>14 to be -- to be -- do you consider yourself to be</p> <p>15 an expert on the mineralogy of talc?</p> <p>16 A. No, I do not.</p> <p>17 Q. You are not a geneticist, correct?</p> <p>18 A. That is correct.</p> <p>19 Q. You're not a mineralogist, correct?</p> <p>20 A. That is correct.</p> <p>21 Q. You're not an industrial hygienist,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. You're not an expert in geology,</p>
<p style="text-align: right;">Page 307</p> <p>1 Q. And you've never told a patient that</p> <p>2 her talc use caused her ovarian cancer, correct?</p> <p>3 A. I am not a clinician.</p> <p>4 Q. You've never told a woman not to use</p> <p>5 talc, correct?</p> <p>6 A. Correct. Well, my daughter.</p> <p>7 (Laugh).</p> <p>8 Q. You have told your daughter not to</p> <p>9 use talc?</p> <p>10 A. Yes.</p> <p>11 Q. When did you tell her that?</p> <p>12 A. I don't know. Growing up, when I've</p> <p>13 been doing this work for a long time.</p> <p>14 Q. Other than your daughter, have you</p> <p>15 ever told a woman not to use talc?</p> <p>16 A. No.</p> <p>17 Q. Have you ever recommended to any</p> <p>18 physician that they tell their patients not to use</p> <p>19 talcum powder --</p> <p>20 A. No.</p> <p>21 Q. -- in the genital area?</p> <p>22 A. No.</p> <p>23 Q. You are not an expert in toxicology;</p> <p>24 is that a fair statement?</p>	<p style="text-align: right;">Page 309</p> <p>1 correct?</p> <p>2 A. No.</p> <p>3 Q. You have not studied where you can</p> <p>4 say you're an expert on Johnson's Baby Powder,</p> <p>5 that is, where it's mined from, how it's</p> <p>6 processed, how it's tested, things like that?</p> <p>7 A. No, only what I've read in the</p> <p>8 literature.</p> <p>9 Q. Have you read in the literature the</p> <p>10 details of where Johnson &amp; Johnson has -- has had</p> <p>11 its talc mined from, what the processes are for</p> <p>12 mining and processing the talc, what tests have</p> <p>13 been done for asbestos? Have you read that in the</p> <p>14 literature?</p> <p>15 A. I don't think so.</p> <p>16 Q. With regard to the methodology that</p> <p>17 you set out in your report, have you ever taught</p> <p>18 that methodology to any students?</p> <p>19 A. Yes.</p> <p>20 Q. In what class have you taught that</p> <p>21 methodology and when was the last time you taught</p> <p>22 it?</p> <p>23 A. I just finished teaching it this</p> <p>24 spring. "Guided Epidemiology Research."</p>

<p style="text-align: right;">Page 310</p> <p>1 Q. And in that course on "Guided 2 Epidemiology Research," did you go through the 3 methodology you describe in your report? 4 A. Yes. The students come up, develop 5 a research question, analyze data for a particular 6 hypothesis, analyze the data, and then interpret 7 the findings. And during the interpretation of 8 the findings, they go through the process of 9 determining whether or not they believe the 10 findings to be true or spurious based on the same 11 criteria that I used in determining the -- the 12 scientific integrity of the talc and ovarian 13 cancer association. 14 Q. What level of student did you teach 15 that to? 16 A. These are master's level students. 17 Q. Outside of your presentation to FDA 18 at the workshop back in 1994, have you ever 19 lectured to your peers with regard to your 20 opinions on talc and ovarian cancer? 21 A. I may have given a seminar on the 22 research because I have a body of research that I 23 had done at that time, but certainly not recently. 24 Q. You say --</p>	<p style="text-align: right;">Page 312</p> <p>1 Q. We've talked a little bit about 2 statistical significance. 3 You agree that statistical 4 significance using a p-value of .05 is an 5 important evaluation in an epidemiologic study? 6 A. No, I do not agree with that. 7 It is an arbitrary dichotomous cut 8 point that merely represents that the risk 9 estimate 95 percent of the time will fall between 10 a lower confidence bound and an upper confidence 11 bound. And if that lower confidence bound is 0.99 12 and the upper confidence bound is 1.45, then to 13 deem it not statistically significant is 14 inappropriate. 15 Q. Is a p-value of .05 still the 16 standard for determining whether a study shows an 17 association between an exposure and a disease? 18 A. It is a tool that is used, but not 19 one that is relied upon for assessing causation. 20 Q. Going back to my question, though. 21 From your standpoint, is it still an 22 industry standard for showing whether there's an 23 association between an exposure and a disease? 24 MR. TISI: Objection to the</p>
<p style="text-align: right;">Page 311</p> <p>1 A. And I can't think of any, and you 2 can look -- we can look in my CV and see if there 3 are any invited presentations that were specific 4 about ovarian cancer risk factors. If -- if 5 they're not in the CV, then I didn't do it. 6 Q. Sitting here today, outside of the 7 presentation you gave at FDA, do you recall giving 8 that kind of presentation or a similar 9 presentation on talc and ovarian cancer to any 10 other group or set of your peers or colleagues? 11 A. I -- unless it's in my CV, I have 12 not, and anything -- and I would not have done 13 that in a -- in a nonscientific setting. 14 Q. With regard to the methodology you 15 applied in this case, is there any ability to test 16 whether it is a reliable methodology for reaching 17 causation conclusions? 18 MR. TISI: Objection. 19 THE WITNESS: I don't think 20 there is a test. It is the way that we 21 in epidemiology teach and carry out our 22 research. It is the standard of 23 practice. 24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 313</p> <p>1 term "industry standard." This is a 2 profession, not an industry, but go 3 ahead. 4 THE WITNESS: The standard is 5 to be able to show the point estimate and 6 what the 95 percent confidence interval 7 is. That is the standard in 8 epidemiologic research. Not to show a 9 point estimate and then to indicate that 10 it happens to be greater than or less 11 than P 0.05. 12 BY MR. HEGARTY: 13 Q. In looking at relative risk, one is 14 considered the null value, indicating no 15 association, correct? 16 A. Correct. 17 Q. If a study is not statistically 18 significant, it means the result could be due to 19 random chance, correct? 20 MR. TISI: Objection. 21 THE WITNESS: I think I 22 believe I stated before that any result, 23 regardless of statistical significance, 24 could be due to chance or bias.</p>

<p style="text-align: right;">Page 314</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Going back to the null value of 1.</p> <p>3 If the confidence interval contains the value of</p> <p>4 1, then the true finding, as I mentioned earlier,</p> <p>5 could be 1.0, correct?</p> <p>6 A. The true value could be anywhere</p> <p>7 from the lowest confidence bound to the highest</p> <p>8 confidence bound.</p> <p>9 Q. Do you agree that there are</p> <p>10 generally three categories of phenomena that could</p> <p>11 result in an association finding in a study to be</p> <p>12 erroneous: chance, bias, and confounding?</p> <p>13 A. Well, confounding is bias. So</p> <p>14 chance is certainly one. Confounding is certainly</p> <p>15 one. But within the category of bias, there are a</p> <p>16 number of different components that are there,</p> <p>17 such as misclassification, selection bias, things</p> <p>18 like that.</p> <p>19 Q. Is there any way to account for</p> <p>20 chance in an epidemiologic study besides</p> <p>21 statistical significance?</p> <p>22 MR. TISI: In an individual</p> <p>23 study or in studies overall?</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 316</p> <p>1 A. With the exposure, yes. The</p> <p>2 exposure of interest and the outcome, yes.</p> <p>3 Q. In every study there exists the</p> <p>4 potential for unknown confounders, correct?</p> <p>5 A. Yes, possibly.</p> <p>6 Q. When considering bias and</p> <p>7 confounders, the weaker the association, that is,</p> <p>8 the closer it is to 1.0, the greater the concern</p> <p>9 is that bias or confounding could be the reason</p> <p>10 for that association, correct?</p> <p>11 A. Yes, certainly greater -- I mean,</p> <p>12 attention should be paid regardless of whether it</p> <p>13 is an association of 1.3, 2.0, 3.0. We always use</p> <p>14 the same method to determine how reliable that</p> <p>15 estimate is based on potential sources of bias --</p> <p>16 Q. And association --</p> <p>17 A. -- and confounding.</p> <p>18 Q. Finding association does not mean</p> <p>19 causation, correct?</p> <p>20 A. That is correct.</p> <p>21 Q. A risk factor is not necessarily a</p> <p>22 causal factor, correct?</p> <p>23 A. That is correct.</p> <p>24 Q. Going back to your methodology</p>
<p style="text-align: right;">Page 315</p> <p>1 Q. Well, did you understand my</p> <p>2 question?</p> <p>3 A. Why don't --</p> <p>4 MR. TISI: I need to</p> <p>5 understand it. It needs to be clear. So</p> <p>6 is it --</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Is there any way in an epidemiologic</p> <p>9 study to account for chance other than through</p> <p>10 statistical significance?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: Accounting for</p> <p>13 -- statistical significance is not a way</p> <p>14 to determine whether chance is the</p> <p>15 explanation for the finding.</p> <p>16 The way to determine whether</p> <p>17 chance is the explanation for the finding</p> <p>18 is to look at other known factors that</p> <p>19 could be influencing the association.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Confounding is where there could be</p> <p>22 another association present within the study that</p> <p>23 confuses the relationship between the agent of</p> <p>24 interest and the outcome of interest, correct?</p>	<p style="text-align: right;">Page 317</p> <p>1 section in your report.</p> <p>2 A. Uh-huh.</p> <p>3 Q. What is the objective criteria that</p> <p>4 you apply for this methodology?</p> <p>5 MR. TISI: Objection. Asked</p> <p>6 and answered a couple times.</p> <p>7 You may answer it again.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. Let me put -- let me ask a different</p> <p>10 way because that may be unclear.</p> <p>11 Isn't your methodology subjective</p> <p>12 based on the person who's conducting it? And if</p> <p>13 so -- if not, why not?</p> <p>14 MR. TISI: Objection. Asked</p> <p>15 and answered a couple times.</p> <p>16 THE WITNESS: I wouldn't -- I</p> <p>17 wouldn't say it's subjective.</p> <p>18 I would say it's objective.</p> <p>19 There's no qualitative process. I mean,</p> <p>20 it's -- it's evaluation of quantitative</p> <p>21 data.</p> <p>22 So looking at the strength of</p> <p>23 the association in terms of the -- the</p> <p>24 range in which the confidence interval,</p>



<p style="text-align: right;">Page 318</p> <p>1 the estimate falls; looking at the extent  2 possible whether there's an increasing  3 association with increasing levels of  4 exposure, whether there's biological  5 plausibility and potential for explaining  6 the association, whether there's a  7 temporal issue, and whether there is  8 consistency across multiple studies is  9 certainly a standard that we do, in  10 conjunction with trying to explain other  11 non-causal explanations for all of those  12 findings.  13 So I believe that's -- that's  14 my response to your question.  15 BY MR. HEGARTY:  16 Q. Turn over to page 5 of your report.  17 A. Yes.  18 Q. At the very top.  19 A. Yes.  20 Q. You write that:  21 "The point is that epidemiologists  22 make their inferences by pitting alternative  23 explanations against one another. This approach  24 amounts to pitting non-causal theories against a</p>	<p style="text-align: right;">Page 320</p> <p>1 could have been present, and even those that may  2 be unrecognized.  3 Q. You told me that you applied this  4 methodology in your studies on talc and ovarian  5 cancer?  6 A. Yes.  7 Q. Let me ask in a different way.  8 Have you ever described the process  9 of this methodology, without regard to the  10 exposure and the disease you're looking at, in any  11 written publication of yours?  12 A. No.  13 MR. TISI: Objection.  14 THE WITNESS: No, I haven't,  15 but it is a standard of practice that's  16 indicated in epidemiology methods  17 textbooks in the approach.  18 It is the foundation of  19 epidemiologic research.  20 BY MR. HEGARTY:  21 Q. Is this methodology, as you can  22 recall, described in Dr. Rothman's textbook?  23 A. Yes. Certainly all these components  24 related to the biases.</p>
<p style="text-align: right;">Page 319</p> <p>1 causal theory. Epidemiologists ask, 'Is there  2 some systematic error in the data from a study?  3 Then let's control that problem to see what  4 association if any remains between exposure and  5 disease.'  6 Did I read that correctly?  7 A. You did.  8 Q. So is it -- so are you saying there  9 that there is an association -- that an  10 association is causal unless it can be explained  11 by some systematic error?  12 A. It may very well be causal if after  13 all -- well, it may be assumed to be causal after  14 explaining all of the potential explanations for  15 the association, and that includes systematic  16 error in the data.  17 Q. Is that how you reached your  18 opinions in this case, by controlling or  19 accounting for systematic error?  20 A. We -- we didn't quantitatively do  21 that. We looked to see if it had been done in the  22 studies and made our assessments based on issues  23 related to -- to misclassification of the exposure  24 and confounding and other sources of bias that</p>	<p style="text-align: right;">Page 321</p> <p>1 Q. Please turn over to paragraph 20 --  2 I'm sorry -- to page 20 of your report.  3 A. Yes.  4 Q. Do you cite at the top the factors  5 that you rely upon for reaching your opinions in  6 this case?  7 A. Uh-huh.  8 Q. Yes?  9 A. Yes.  10 Q. We talked about this a little bit  11 earlier, but at the top of page 20 you say that  12 "Considering the preponderance of the evidence,  13 including" and then you cite prepared at B --  14 A. I'm sorry. Where is this? The  15 sentence?  16 Q. Yeah. Very top.  17 A. Oh, "Considering." Yes, yes, yes.  18 Yes.  19 Q. "Including" and then going to  20 paragraph B.  21 "After controlling for known risk  22 and protective factors for ovarian cancer,  23 evidence of a trend of increasing risk of ovarian  24 cancer with increasing talc applications,</p>

<p style="text-align: right;">Page 322</p> <p>1 especially when the vaginal tract is open to the 2 ovaries." 3       You see where I'm reading? 4       A.    Yes, I do. 5       Q.    And that evidence of a trend that 6 you specifically refer to in your report is from 7 the Cramer 2016 study, correct? 8       MR. TISI: Objection. 9       THE WITNESS: Close. It's 10 from multiple studies. There is the 11 Cramer study. There's my 1992 study. 12 There's Schildkraut study. There's a 13 number of studies that have shown this. 14 BY MR. HEGARTY: 15       Q.    And you mentioned Schildkraut. Let 16 me clarify my question. 17       A.    Yeah. 18       Q.    The only two studies you actually 19 specifically refer to in your report as shown as 20 being a preponderance of the evidence are the 21 Cramer and Schildkraut studies, correct? 22       A.    That's what's listed in the report. 23 Although in the description of the meta-analyses, 24 there may have been some discussion of dose</p>	<p style="text-align: right;">Page 324</p> <p>1       A.    Well, in the O'Brien study that 2 looked at all the cohort studies together, they 3 recognized that the association was, in their 4 view, statistically significant in those with 5 patent genital tracts, and that's a compilation of 6 all three of the cohort studies, despite the fact 7 that the cohort studies are flawed in terms of 8 exposure assessment. 9       Q.    If we look at the findings in the 10 cohort studies as to ovarian cancer and talc use 11 overall, none of those studies reported a 12 statistically significant association between talc 13 use ever never and ovarian cancer, correct? 14       MR. TISI: Objection. 15       THE WITNESS: Well, that's 16 correct, but it's largely because the 17 associations that as we talked about in 18 our report are attenuated because of the 19 issue of misclassification. 20       And particularly the issue 21 of -- of selection bias, such as in the 22 Sister Study where 160 or so women with 23 ovarian cancer were excluded from the 24 analyses because they already had ovarian</p>
<p style="text-align: right;">Page 323</p> <p>1 response. But those are not new data, and this is 2 new data. The other ones are meta-analyses. 3       Q.    Please turn over to the Executive 4 Summary section of your report, which is on 5 page 6. 6       A.    Uh-huh. 7       Q.    Second paragraph, the middle of that 8 paragraph you make the sentence -- you make the 9 statement: 10       "We note that there is also an 11 association between talc use and ovarian cancer in 12 cohort studies." 13       Do you see where I'm reading? 14       A.    I do. 15       Q.    Do any of the cohort studies 16 themselves say that there is an association 17 between talc use and ovarian cancer? 18       A.    Yes, the Nurses' Health Study shows 19 it. 20       Q.    My question, though, is very 21 specific. 22       My question is: Do the authors 23 state in their studies that they show an 24 association between talc use and ovarian cancer?</p>	<p style="text-align: right;">Page 325</p> <p>1 cancer, and they only followed up those 2 who hadn't already had ovarian cancer 3 and, therefore, you have a depletion of 4 susceptibles in that and so you wouldn't 5 -- you would already be underestimating 6 the risk. 7       And the WHI, as I indicated, 8 had women who weren't enrolled in the 9 study until after age 50. About half of 10 ovarian cancers occur before the age of 11 50. 12       So, so I'm not surprised that 13 the associations are attenuated in the 14 cohort studies. 15 BY MR. HEGARTY: 16       Q.    Can you cite for me any author in 17 any published literature who has said that the 18 cohort studies showed an association between talc 19 use and ovarian cancer? 20       A.    Other than in the Gertig article 21 where they did say for those -- those with a -- 22 with serous tumors had an association they thought 23 was statistically significant, I believe. Yeah. 24       Q.    Anywhere else besides Gertig as to</p>

<p style="text-align: right;">Page 326</p> <p>1 serous invasive ovarian cancer?</p> <p>2 A. And the joint analysis that O'Brien</p> <p>3 did with respect to patent -- open patent tracts.</p> <p>4 Q. In your "Case-control studies"</p> <p>5 section at page 8, you talk about the lengths --</p> <p>6 length of study, correct? Lengths of study.</p> <p>7 A. Under "Case-control studies"?</p> <p>8 Q. Yes, page 8.</p> <p>9 A. Oh, I'm sorry.</p> <p>10 Q. At the top.</p> <p>11 A. Yes.</p> <p>12 MR. HEGARTY: I'm going to</p> <p>13 show you the Langseth 2008 study, which I</p> <p>14 marked as Exhibit 21.</p> <p>15 (Document marked for</p> <p>16 identification as Harlow Exhibit 21.)</p> <p>17 THE WITNESS: Yeah. Yep.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. In this study, the authors reported</p> <p>20 heterogeneity between the hospital and the</p> <p>21 population-based studies, correct?</p> <p>22 A. Yes.</p> <p>23 Q. That means that the combined results</p> <p>24 of those studies were different from a statistical</p>	<p style="text-align: right;">Page 328</p> <p>1 was not statistically significant, correct?</p> <p>2 A. The confidence interval did include</p> <p>3 1.0, but there -- but it should be noted that</p> <p>4 hospital control -- use of hospital controls can</p> <p>5 often attenuate the association because the reason</p> <p>6 for them being in the hospital could be related or</p> <p>7 could be a confounding factor on things that</p> <p>8 influence women's gynecologic cancers.</p> <p>9 So, you know, I'm not surprised</p> <p>10 that -- that we see a little bit of a difference</p> <p>11 there.</p> <p>12 Q. You had done hospital-control</p> <p>13 studies yourself, correct? Hospital-based control</p> <p>14 studies?</p> <p>15 A. Most of my research has been</p> <p>16 population-based. I'm trying to think about my</p> <p>17 study in 1989. I know that was cancer</p> <p>18 population-based cases. Did I use?</p> <p>19 Because all my other research</p> <p>20 outside of ovarian cancer has been</p> <p>21 population-based, but let me just see in the --</p> <p>22 those tumors. Let me see.</p> <p>23 (Reviews document.)</p> <p>24 Yeah, population-based.</p>
<p style="text-align: right;">Page 327</p> <p>1 standpoint, correct?</p> <p>2 A. Oh, can I see the -- the exhibit?</p> <p>3 Oh, here we go.</p> <p>4 Q. Take a look at Figure 1.</p> <p>5 A. Yeah, here we go.</p> <p>6 Right. Right. So the question?</p> <p>7 Q. Let me start -- ask it a different</p> <p>8 way.</p> <p>9 None of the hospital studies showed</p> <p>10 a statistically significant increase in risk</p> <p>11 between talc use and ovarian cancer, correct?</p> <p>12 MR. TISI: Objection.</p> <p>13 THE WITNESS: Well, the pooled</p> <p>14 analysis for the hospital-based study was</p> <p>15 1.12 with a confidence interval of 0.92</p> <p>16 to 1.36, which means that falls somewhere</p> <p>17 in between there. So that's what their</p> <p>18 finding was there.</p> <p>19 And then for the pooled odds</p> <p>20 ratios for the case -- for the</p> <p>21 population-based studies, it was 1.4 with</p> <p>22 a confidence interval of 1.29 to 1.52.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. The hospital-based pooled analysis</p>	<p style="text-align: right;">Page 329</p> <p>1 Q. Okay.</p> <p>2 A. So I've really done all</p> <p>3 population-based research.</p> <p>4 Q. Did you read the Langseth article</p> <p>5 when it came out in 2008?</p> <p>6 A. Not in 2008.</p> <p>7 Q. Had you read it prior to being</p> <p>8 contacted by plaintiffs' counsel in this case</p> <p>9 about serving as an expert witness?</p> <p>10 A. No, I had not.</p> <p>11 Q. Please look at the section under</p> <p>12 "Proposal to Research Community."</p> <p>13 A. Yes.</p> <p>14 Q. That proposal says that:</p> <p>15 "The current body of experimental</p> <p>16 and epidemiological evidence is insufficient to</p> <p>17 establish a causal association between perineal</p> <p>18 use of talc and ovarian cancer risk."</p> <p>19 Was that a fair conclusion from the</p> <p>20 data they reported here back in 2008?</p> <p>21 MS. PARFITT: Objection.</p> <p>22 THE WITNESS: Yeah. Well, no,</p> <p>23 I'm not sure I agree with that.</p> <p>24 When you look at all of the</p>

<p style="text-align: right;">Page 330</p> <p>1 studies, particularly the</p> <p>2 population-based studies, which are the</p> <p>3 ones that are more of a gold standard</p> <p>4 approach for epidemiological research,</p> <p>5 every one of the estimates are above 1</p> <p>6 with a very narrow confidence interval of</p> <p>7 1.3 to 1.5.</p> <p>8 So to say that the current</p> <p>9 body of epidemiologic evidence is</p> <p>10 insufficient is not, in my view, correct.</p> <p>11 The experimental I can't -- I can't, you</p> <p>12 know, make a comment on.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. If you look over at the left-hand</p> <p>15 side of page 359.</p> <p>16 A. Yes.</p> <p>17 Q. The middle paragraph.</p> <p>18 A. Yes.</p> <p>19 Q. Towards the bottom. They make the</p> <p>20 statement that:</p> <p>21 "The main epidemiological evidence</p> <p>22 against the association is the absence of clear</p> <p>23 exposure-response associations in most study, as</p> <p>24 well as the absence of an overall excess risk in</p>	<p style="text-align: right;">Page 332</p> <p>1 about this or should be told to look for</p> <p>2 alternative methods.</p> <p>3 I believe in 1999 I may have made</p> <p>4 the same recommendations. I even raised concerns</p> <p>5 in 1989.</p> <p>6 So have I -- do we need to have</p> <p>7 definitively determined causation in order for us</p> <p>8 to have informed women of the risk, potential risk</p> <p>9 of using a product that had no reasonable --</p> <p>10 that -- that was not therapeutic or necessary with</p> <p>11 an alternative available? I think I did my best</p> <p>12 to try to provide that warning.</p> <p>13 MR. HEGARTY: I want to next</p> <p>14 show you a study with a first author</p> <p>15 Rosenblatt dated from 2011 I marked as</p> <p>16 Exhibit Number 22.</p> <p>17 (Document marked for</p> <p>18 identification as Harlow Exhibit 22.)</p> <p>19 THE WITNESS: Yes, thank you.</p> <p>20 Let me see if I have</p> <p>21 Rosenblatt in here. Yeah.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. You read the Rosenblatt study as</p> <p>24 part of your work on this case; is that correct?</p>
<p style="text-align: right;">Page 331</p> <p>1 the cohort study."</p> <p>2 Were those true statements back in</p> <p>3 2008?</p> <p>4 A. I'm not sure what they mean by</p> <p>5 "exposure-response," which I think they mean is</p> <p>6 with increasing exposure, you see a greater risk</p> <p>7 of the disease.</p> <p>8 And, again, my article in 1992, in</p> <p>9 1999, other articles that have shown a dose</p> <p>10 response are not -- were present.</p> <p>11 So could we have more? Yes, I'd</p> <p>12 love there to have been more. But is there enough</p> <p>13 for us to be concerned about this exposure? Yes.</p> <p>14 And then -- and then the absence of</p> <p>15 an overall excess risk in the cohort study, I've</p> <p>16 talked about that.</p> <p>17 Q. Have you done an analysis of when</p> <p>18 you believe the evidence was sufficient over the</p> <p>19 years to say that there was -- there is -- was a</p> <p>20 causal relationship or there is a causal</p> <p>21 relationship between talc use and ovarian cancer?</p> <p>22 A. I did not do a causal inference</p> <p>23 analysis; but in my papers, particularly 1992, I</p> <p>24 believe I recommended that women should be warned</p>	<p style="text-align: right;">Page 333</p> <p>1 A. I did, but I'm trying to see if it's</p> <p>2 cited. I don't know that it was cited in my</p> <p>3 report. So let's just see if it was.</p> <p>4 No. I'm aware of this study. I'm</p> <p>5 aware of this study, but I did not -- it was not</p> <p>6 in my -- in my report.</p> <p>7 Q. One of the authors of the study is</p> <p>8 Noel Weiss?</p> <p>9 A. That's correct.</p> <p>10 Q. He is your primary mentor, correct?</p> <p>11 A. He was, correct.</p> <p>12 Q. He was your primary mentor, correct?</p> <p>13 A. Yes, he was.</p> <p>14 Q. How would you characterize his</p> <p>15 capabilities as an epidemiologist?</p> <p>16 A. Outstanding.</p> <p>17 Q. Is he a reliable -- was he a</p> <p>18 reliable authority with regard to epidemiology?</p> <p>19 A. With respect to epidemiology? Yes.</p> <p>20 Q. Did you read the Rosenblatt study at</p> <p>21 the time it came out in 2011?</p> <p>22 A. I can't recall if I did.</p> <p>23 Q. You said he was your mentor.</p> <p>24 Was he one of your teachers?</p>

<p style="text-align: right;">Page 334</p> <p>1 A. Yes, and he was my dissertation 2 advisor. 3 Q. So you had great respect for him? 4 A. Yes, I do. 5 Q. Looking in the "Abstract" of this 6 paper, that looked at genital powder exposure and 7 the risk of epithelial ovarian cancer. 8 A. Uh-huh. 9 Q. Towards the bottom. 10 A. Uh-huh. 11 Q. The authors, including Dr. Weiss, 12 say: 13 "We noted no clear pattern of risk 14 increase on the basis of the extent of use, 15 assessed as years in which powder was used, or as 16 lifetime number of applications for invasive or 17 borderline tumors, or their histologic subtypes." 18 That's a correct statement from what 19 their data showed, correct? 20 A. Actually -- 21 MR. TISI: Objection. Please 22 take a moment and look at the study. 23 THE WITNESS: No, I'm looking 24 at it, and I can tell you that for all</p>	<p style="text-align: right;">Page 336</p> <p>1 and in some previous ones, but that association 2 generally has not been consistent within or among 3 studies. Therefore, no stronger adjective than 4 'possible' appears warranted at this time." 5 Do you disagree with those 6 conclusion statements? 7 A. Oh, not -- I don't necessarily 8 disagree with it, but this was in 2011 and there 9 have been a number of studies and meta-analyses 10 that have been done since then. 11 Q. Were these true statements back in 12 2011? 13 A. In terms of saying that "possible 14 appears warranted at this time"? I would have 15 been a little bit stronger in my term. 16 Q. What stronger term would you have 17 used? 18 A. Feasible, but I'm okay with that. 19 Q. Turning over to page 739. 20 A. Yes. 21 Q. In the "Results" section on the 22 right-hand column, first full paragraph. The 23 authors write: 24 "We noted no evidence that risk of</p>
<p style="text-align: right;">Page 335</p> <p>1 tumors, those who used powder after 2 bathing had a 1.27 excess risk after 3 adjustment for, you know, the most 4 important risk factors with a confidence 5 interval of 0.97 to 1.66. 6 BY MR. HEGARTY: 7 Q. The part of the abstract I read to 8 you, though, was in regards to dose response, 9 correct? 10 A. (Reviews document.) 11 Right, but they didn't take it -- 12 yes, but they did not take into account times when 13 the genital tract was open. They did not consider 14 issues with respect to ovulation. They did not 15 consider whether or not they had -- whether 16 exposures occurred before or after a tubal 17 ligation or hysterectomy. 18 Q. Please look at the "Conclusions" 19 section in the abstract on page 1. 20 A. Uh-huh. 21 Q. The authors write, including 22 Dr. Weiss, that: 23 "A modest association of ovarian 24 cancer with this exposure was seen in our study</p>	<p style="text-align: right;">Page 337</p> <p>1 ovarian cancer increased in association with 2 increasing extent of the use of perineal dusting 3 powder (assessed as years in which powder was used 4 or as lifetime number of applications) for either 5 invasive or borderline tumors." 6 Did I read that correctly? 7 A. Yes, you did. 8 Q. Is that an accurate summary of their 9 evidence with regard to increasing -- with regard 10 to whether an association increased with the 11 increasing extent of use? 12 A. Yes, based on their data. Uh-huh. 13 Q. Please turn over to the "Discussion" 14 section on page 741. 15 A. Well, but if you also look in that 16 paragraph, risk was increased among women who 17 first reported the regular use of perineal dusting 18 powders at age 30 years or older. Odds ratio for 19 invasive borderline tumors of 1.69 on women whose 20 first regular use was in 1980 or later, and there 21 they also showed a very strong association with 22 borderline ovarian tumors. 23 So I think it's important to look at 24 the -- at all of the findings in the context here.</p>



<p style="text-align: right;">Page 338</p> <p>1 Q. Those statements you described do</p> <p>2 not pertain to dose response, correct?</p> <p>3 A. Well, not -- not in the way in which</p> <p>4 they did it, but it could indicate longer periods</p> <p>5 of time of exposure.</p> <p>6 Q. Please look over to the "Discussion"</p> <p>7 section.</p> <p>8 A. Uh-huh.</p> <p>9 Q. The first paragraph, the authors</p> <p>10 write:</p> <p>11 "A number of case-control studies of</p> <p>12 ovarian cancer, in addition to ours, have examined</p> <p>13 the issue of genital powder exposure as a</p> <p>14 potential risk factor. The validity of all of</p> <p>15 these studies, including ours, may be influenced</p> <p>16 by the level of non-response among cases and</p> <p>17 controls, and by the potential for</p> <p>18 misclassification (differential and</p> <p>19 non-differential) of exposure status."</p> <p>20 Are those two accurate statements?</p> <p>21 A. They're always possible.</p> <p>22 Q. Please turn over to the next page.</p> <p>23 A. But I think it's important to point</p> <p>24 out that when you make a statement like that, you</p>	<p style="text-align: right;">Page 340</p> <p>1 to look at the whole paragraph.</p> <p>2 THE WITNESS: Yes. Yeah,</p> <p>3 yeah.</p> <p>4 (Reviews document.)</p> <p>5 Okay. Could you repeat the</p> <p>6 question?</p> <p>7 BY MR. HEGARTY:</p> <p>8 Q. Sure.</p> <p>9 The two statements or the statement</p> <p>10 I read beginning:</p> <p>11 "However, a non-causal</p> <p>12 interpretation."</p> <p>13 A. Uh-huh.</p> <p>14 Q. Are those accurate statements?</p> <p>15 A. Well, no, not in terms of -- it's --</p> <p>16 it's -- sorry, Noel, but I'm not sure I agree with</p> <p>17 focusing on the overall association, when in that</p> <p>18 same article they provide exposure assessments in</p> <p>19 different ways and more appropriate ways. So I</p> <p>20 think that is a bit incomplete.</p> <p>21 And then when they talk about the</p> <p>22 absence in most studies, including the current</p> <p>23 study, of the trend with increasing duration of</p> <p>24 exposure, they cite Langseth and they don't cite</p>
<p style="text-align: right;">Page 339</p> <p>1 should probably provide a little more information</p> <p>2 as to what those potential -- what potential</p> <p>3 examples might be.</p> <p>4 Q. Please turn over to the next page.</p> <p>5 The first full paragraph beginning</p> <p>6 "In support of."</p> <p>7 A. Yeah.</p> <p>8 Q. You see that paragraph?</p> <p>9 A. Yes.</p> <p>10 Q. The second sentence says:</p> <p>11 "However, a non-causal</p> <p>12 interpretation may be consistent with the absence</p> <p>13 of an overall association in the one cohort study</p> <p>14 of the question, along with the absence in most</p> <p>15 studies (including the current study) of a trend</p> <p>16 of increasing risk with increasing duration of</p> <p>17 exposure."</p> <p>18 Do you agree with those statements?</p> <p>19 MR. TISI: Again, why don't</p> <p>20 you take a look at the whole paragraph.</p> <p>21 I mean, he's just picking out sentences.</p> <p>22 THE WITNESS: I know. We're</p> <p>23 talking about the Gertig study.</p> <p>24 MR. TISI: No, but feel free</p>	<p style="text-align: right;">Page 341</p> <p>1 the multiple studies -- mine in particular in</p> <p>2 1992, 1999 -- as fact evidence.</p> <p>3 So are we to make our decision on</p> <p>4 causality based on one study? I don't believe so.</p> <p>5 We look at it in the package of all studies that</p> <p>6 have been done because there are a lot of issues</p> <p>7 that could be at play as to why one study seems to</p> <p>8 be somewhat different from another.</p> <p>9 Q. I'm finished with that study.</p> <p>10 A. Okay.</p> <p>11 MR. HEGARTY: The next study I</p> <p>12 want to refer to is one you also</p> <p>13 discussed in your expert report.</p> <p>14 THE WITNESS: Uh-huh.</p> <p>15 MR. HEGARTY: The 2013 study</p> <p>16 by Terry --</p> <p>17 THE WITNESS: Yes. The pooled</p> <p>18 analysis, yes.</p> <p>19 MR. HEGARTY: -- which I</p> <p>20 marked as Exhibit Number 23.</p> <p>21 (Document marked for</p> <p>22 identification as Harlow Exhibit 23.)</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. This is a study you comment on in</p>

<p style="text-align: right;">Page 342</p> <p>1 your expert report?</p> <p>2 A. Yes. Uh-huh.</p> <p>3 Q. This is a pooled study of</p> <p>4 case-control data; is that correct?</p> <p>5 A. Yes.</p> <p>6 Q. Please turn to page 820.</p> <p>7 A. Uh-huh.</p> <p>8 While you're getting that together,</p> <p>9 could we go off the record?</p> <p>10 MR. HEGARTY: Yes, we can.</p> <p>11 (Recess: 4:07 p.m. -</p> <p>12 4:21 p.m.)</p> <p>13 MR. HEGARTY: We are back on</p> <p>14 the record.</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. Doctor, I had asked you previously</p> <p>17 about presentations that you may have talked about</p> <p>18 talcum powder use and ovarian cancer.</p> <p>19 Did you look at your CV to see if</p> <p>20 you found a presentation where that might have</p> <p>21 come up?</p> <p>22 A. Yes. Yes, I did.</p> <p>23 Q. What did you find?</p> <p>24 A. In 1998 I believe. It was open a</p>	<p style="text-align: right;">Page 344</p> <p>1 A. Am I in the right study? Hold on.</p> <p>2 Q. Terry.</p> <p>3 A. Yeah, 819 is just graphs. Oh, no,</p> <p>4 819. Yes, I'm sorry. Yeah. Left-hand column.</p> <p>5 Yes. Sorry.</p> <p>6 Q. They note that with regard to</p> <p>7 restricting their analysis to genital powder</p> <p>8 applications that occurred before tubal ligation</p> <p>9 or hysterectomy made no substantive difference in</p> <p>10 the results, correct?</p> <p>11 A. (Reviews document.)</p> <p>12 "That occurred before tubal ligation</p> <p>13 or hysterectomy made no substantive difference in</p> <p>14 the results."</p> <p>15 And I'd like to see that data for</p> <p>16 studies that collected data on timing.</p> <p>17 This was -- if you'll excuse me, I</p> <p>18 just wanted to make sure.</p> <p>19 Q. How long is that going to take you</p> <p>20 to look at that?</p> <p>21 A. What?</p> <p>22 Q. How long will it take you to look at</p> <p>23 that?</p> <p>24 A. Not long but...</p>
<p style="text-align: right;">Page 343</p> <p>1 second ago. But 1998 at the Dana Farber Cancer</p> <p>2 Institute on the epidemiology of ovarian cancer.</p> <p>3 Q. Was that the last time you discussed</p> <p>4 risk factors for ovarian cancer?</p> <p>5 A. Yes.</p> <p>6 Q. That is in a public forum?</p> <p>7 A. That's correct.</p> <p>8 Q. Do you recall if you talked about</p> <p>9 talcum powder use and ovarian cancer at that</p> <p>10 presentation?</p> <p>11 A. I don't recall, but I'm sure that I</p> <p>12 did because it was certainly one of them.</p> <p>13 Yes, 1998, Dana Farber Cancer</p> <p>14 Institute.</p> <p>15 Q. Please look at the Terry study and,</p> <p>16 rather than 820 where I directed you before, go to</p> <p>17 819 of that study.</p> <p>18 A. Uh-huh.</p> <p>19 Q. Left-hand column, first paragraph.</p> <p>20 MR. TISI: I can't find my</p> <p>21 copy of it. I apologize.</p> <p>22 THE WITNESS: 819?</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. Page 819.</p>	<p style="text-align: right;">Page 345</p> <p>1 (Reviews document.)</p> <p>2 I'm sorry. I need to see where it</p> <p>3 is.</p> <p>4 (Reviews document.)</p> <p>5 I don't see it in the table.</p> <p>6 Q. You need to look at it before you</p> <p>7 can answer?</p> <p>8 A. No, I can -- I can go ahead and</p> <p>9 answer.</p> <p>10 They -- they -- yes, that's what</p> <p>11 they -- that's what they said. I don't know</p> <p>12 whether or not they looked at that with respect to</p> <p>13 taking it into account, taking into account</p> <p>14 applications. So Table 3.</p> <p>15 (Reviews document.)</p> <p>16 Q. Do you need longer to look at it?</p> <p>17 Let's go off the record.</p> <p>18 A. Yeah, let's go off the record. That</p> <p>19 will be fine. I'm okay with that. I just want to</p> <p>20 make sure that --</p> <p>21 MR. TISI: I'm actually not.</p> <p>22 THE WITNESS: Sorry.</p> <p>23 MR. TISI: I want you to stay</p> <p>24 on the record.</p>

<p style="text-align: right;">Page 346</p> <p>1 MR. HEGARTY: We're off the</p> <p>2 record.</p> <p>3 MR. TISI: No, we're on the</p> <p>4 record.</p> <p>5 MR. HEGARTY: No, we're off</p> <p>6 the record. Chris, come on. We've</p> <p>7 always done this. If somebody needs more</p> <p>8 time, we've always gone off the record.</p> <p>9 (Recess: 4:25 p.m. -</p> <p>10 4:26 p.m.)</p> <p>11 MR. HEGARTY: We're back on</p> <p>12 the record.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. I pointed you to the statement on no</p> <p>15 difference in between in patients that had a tubal</p> <p>16 ligation or hysterectomy.</p> <p>17 That's what they found; is that</p> <p>18 correct?</p> <p>19 A. I'm sorry. Repeat the question.</p> <p>20 Q. The statement I read to you earlier</p> <p>21 is an accurate statement, correct?</p> <p>22 A. Oh. That "Restricting our exposure</p> <p>23 to genital powder applications that occurred</p> <p>24 before tubal ligation or hysterectomy made no</p>	<p style="text-align: right;">Page 348</p> <p>1 1.32 in the highest -- in the highest level.</p> <p>2 Q. The authors, though, in the</p> <p>3 "Abstract" make the statement on page 1 that:</p> <p>4 "Among genital powder users, we</p> <p>5 observed no significant trend in risk with</p> <p>6 increasing number of lifetime applications."</p> <p>7 Do you see where I'm reading?</p> <p>8 A. On the "Abstract."</p> <p>9 Q. Isn't that the same thing as saying</p> <p>10 they found no dose response?</p> <p>11 A. Well, they're -- again, they're</p> <p>12 doing it based on statistical significance, and I</p> <p>13 disagree with that approach to make the</p> <p>14 interpretation.</p> <p>15 All of the confidence intervals are</p> <p>16 relatively narrow. All of them are at 1.0 or</p> <p>17 higher on the lower bound, and at the highest</p> <p>18 quartile you see at minimum a 16 percent excessive</p> <p>19 risk, which is very consistent from anywhere 16</p> <p>20 percent to 52 percent, which is very consistent</p> <p>21 with those who are the highest exposed component</p> <p>22 of the population.</p> <p>23 Q. Please turn to page 19 of your</p> <p>24 report.</p>
<p style="text-align: right;">Page 347</p> <p>1 substantive difference in the results"?</p> <p>2 Q. Correct.</p> <p>3 That's a correct statement?</p> <p>4 A. Well, that's what they report.</p> <p>5 Q. Did you make reference to that in</p> <p>6 your report or comment on that statement in your</p> <p>7 report?</p> <p>8 A. I don't believe I did. However,</p> <p>9 there is some suggestion that talc use could be</p> <p>10 inhaled and have a deleterious effect in some</p> <p>11 women who are still applying it after -- after</p> <p>12 closure of the genital tract.</p> <p>13 So I suppose there's -- there's</p> <p>14 possible explanations, but the findings are about</p> <p>15 the same and positive in both situations,</p> <p>16 according to the data.</p> <p>17 Q. The Terry study also found no</p> <p>18 increasing trend with increasing dosage, correct?</p> <p>19 A. Actually, that's not true.</p> <p>20 If you look at Table 5 and you look</p> <p>21 at the lower confidence interval, it goes from 1.0</p> <p>22 up to 1.16 and the upper confidence interval</p> <p>23 continues to go up as well. So in my view -- and</p> <p>24 the rates go from 1.14 to 1.23, 1.22 ended up to</p>	<p style="text-align: right;">Page 349</p> <p>1 A. Page 19 of my report.</p> <p>2 Q. In your section on biologic</p> <p>3 plausibility at the bottom.</p> <p>4 Do you see that section?</p> <p>5 A. I do.</p> <p>6 Q. You cite at that part of your report</p> <p>7 a single study discussing talc and the ovaries of</p> <p>8 2019, study by McDonald, correct?</p> <p>9 A. Yes.</p> <p>10 MR. HEGARTY: I'm going to</p> <p>11 mark that as an exhibit.</p> <p>12 Let's go off the record real</p> <p>13 quick.</p> <p>14 (Recess: 4:30 p.m. -</p> <p>15 4:31 p.m.)</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. As I asked you just before we took a</p> <p>18 quick break, you do cite in that part of your</p> <p>19 report a single study by McDonald from 2019,</p> <p>20 correct?</p> <p>21 A. Yes, that's correct.</p> <p>22 MR. HEGARTY: I'll mark that</p> <p>23 study as our next exhibit, which is</p> <p>24 Exhibit 24.</p>

<p style="text-align: right;">Page 350</p> <p>1 (Document marked for 2 identification as Harlow Exhibit 24.) 3 THE WITNESS: Uh-huh. 4 BY MR. HEGARTY: 5 Q. This is the study you rely upon for 6 biologic plausibility between talc use and ovarian 7 cancer, correct? 8 A. It's one of the studies, yes. 9 Q. You state at the end of the 10 paragraph when discussing McDonald, that is, the 11 end of your first paragraph under Section 4 on 12 page 19 that with regard to the patients in the 13 study and talc particles -- just tell me when 14 you're there. 15 A. Yeah, I'm here. 16 Q. With regard to the control patients 17 in the study that none was found and then that no 18 talc was found -- 19 Let me restate that. 20 A. Yeah. 21 Q. You make -- in the last statement of 22 the first paragraph under Section 4, you make the 23 statement that "None" meaning none, no talc 24 particles "were found in the negative exposure</p>	<p style="text-align: right;">Page 352</p> <p>1 MR. TISI: Do you mind me 2 looking over? 3 MR. HEGARTY: No. Please. 4 BY MR. HEGARTY: 5 Q. 598. 6 A. Yeah. 7 Q. In the bottom left-hand corner, it 8 says: 9 "Correlative SEM/EDX of the control 10 tissue blocks showed a total of four talc 11 particles across all patients: two in patient 2 12 and two in patient 3." 13 Do you see where I'm reading? 14 A. I do. 15 Q. That shows that the McDonald study 16 found talc particles in two of the six control 17 patients, correct? 18 A. Yes. 19 Q. So the statement that you made on 20 paragraph 19 under Section 4 that "None was found 21 in the negative exposure controls" is not 22 accurate, correct? 23 A. (Reviews document.) 24 Q. How much time do you need to review</p>
<p style="text-align: right;">Page 351</p> <p>1 controls," correct? 2 A. That's correct. 3 Q. That's not a true statement, is it? 4 A. Well, unless I misread it. I'm 5 happy to re-look at that. 6 Q. Sure. Please look over at 7 Exhibit 24, page 598. 8 MR. TISI: Do you have a copy 9 for me? 10 MR. HEGARTY: Right there. 11 THE WITNESS: Page 598. 12 MR. TISI: That's his. I'm 13 sorry. Did you give him a copy? 14 THE WITNESS: Oh, you may. 15 Yes, this is it. 16 MR. TISI: No, it isn't. 17 MR. HEGARTY: I gave you two 18 copies. 19 THE WITNESS: Oh, I'm sorry. 20 MR. TISI: Did you? All 21 right. 22 MR. HEGARTY: I handed over 23 two copies. 24 THE WITNESS: Okay.</p>	<p style="text-align: right;">Page 353</p> <p>1 the paper, Doctor? 2 A. (Reads document.) 3 I must have -- I must have 4 misquoted. 5 Q. So the McDonald paper actually shows 6 a finding of talc particles in women who had never 7 reported using talcum powder in their ovaries, 8 correct? 9 A. (Reviews document.) 10 Q. I'm sorry. Is that correct, Doctor? 11 A. (Reviews document.) 12 Q. How much time do you need to review 13 the document? 14 A. Just a second, please. 15 (Reviews document.) 16 Well, it appears that they were 17 found in -- in both. Those with and without talc 18 or those with and without exposure to perineal 19 exposure to talc. 20 Q. If studies like this do show talc in 21 the ovaries of women who had never used talcum 22 powder, does that go against a clear finding of 23 biologic plausibility between talcum powder use 24 and ovarian cancer?</p>

<p style="text-align: right;">Page 354</p> <p>1 A. I don't think so. Not necessarily.  2 Particularly given that --  3 (Reviews document.)  4 Particularly given the fact that  5 women who have actually applied it to the genital  6 area have applied it, and those who I believe to  7 be at increased risk have applied it regularly,  8 and there have been -- there's substantial  9 evidence to suggest that the talc has some  10 asbestiform, asbestos contamination.  11 (Reviews document.)  12 Q. Are you finished with your answer?  13 A. I am. I am. I'm just checking to  14 make sure that this is, in fact, the article that  15 I cited.  16 I'm done with mine.  17 Q. Okay. We haven't agreed upon a lot  18 today, Dr. Harlow.  19 A. Yeah.  20 Q. But you do agree that your statement  21 with regard to the McDonald study that "None was  22 found in the negative exposure controls" is  23 incorrect?  24 MR. TISI: Objection. If you</p>	<p style="text-align: right;">Page 356</p> <p>1 not said "none," and I appreciate you  2 giving me a chance to take a look more  3 closely at the article.  4 There was talc found in two of  5 the six controls, but those two had  6 undergone pelvic surgery 30 years before,  7 and the authors suggest that the talc on  8 the surgical gloves could have been  9 responsible for that.  10 And they specifically say that  11 the six control cases supported the  12 contention that talc is rarely found in  13 surgically resected pelvic tissues from  14 patients with no prior perineal or body  15 use exposure.  16 The four talc particles found  17 by the SEM/EDX were in only two patients,  18 both of whom had undergone pelvic surgery  19 procedures more than 30 years ago. And  20 given that history and timeline, the talc  21 could have been introduced from the  22 ambient environment.  23 So I agree that I misspoke  24 when I said none of the controls, but</p>
<p style="text-align: right;">Page 355</p> <p>1 need time to review the paper, feel free  2 to go off the record and we can do that.  3 THE WITNESS: I would like to  4 go off the record. It's going to --  5 MR. HEGARTY: Okay. Let's go  6 off the record. Sure.  7 THE WITNESS: -- take another  8 short look.  9 (Recess: 4:37 p.m. -  10 4:44 p.m.)  11 MR. HEGARTY: We are back on  12 the record.  13 BY MR. HEGARTY:  14 Q. We took a break.  15 Doctor, I commented that you and I  16 have not agreed on a lot of things here today, but  17 can we agree that your statement that "None was  18 found in the negative exposure controls" in  19 reference to the McDonald 2019 study is an  20 inaccurate statement?  21 MR. TISI: Objection.  22 THE WITNESS: Yeah. I think  23 it's important to point out.  24 I probably -- I should have</p>	<p style="text-align: right;">Page 357</p> <p>1 clearly this would not provide evidence  2 against the biological plausibility.  3 BY MR. HEGARTY:  4 Q. At the end of this section on  5 biologic plausibility in your report -- I'm  6 looking at the bottom of page 19.  7 A. Uh-huh.  8 Q. You make the statement that:  9 "Although the exact mechanism --  10 exact pathogenic mechanism by which talc may incur  11 carcinogenesis is unknown, plausible mechanisms  12 may involve inflammation."  13 Do you see where I'm reading?  14 A. I do.  15 Q. You don't cite in this part of your  16 report, or anywhere else within the body of your  17 report, any studies that talk about talc and  18 inflammation, correct?  19 A. Well, in my -- in my review of talc  20 of the association in the 1994 review article, we  21 do talk about inflammation, and there are a number  22 of -- of articles that have suggested that  23 inflammation is a plausible mechanism by which  24 talc could induce ovarian cancer, particularly</p>



<p style="text-align: right;">Page 358</p> <p>1 when talc is embedded in the -- in the inclusion  2 cysts after ovulation and basically remain there  3 and lead to an inflammatory process.  4 Q. Listen to my question, though,  5 Doctor.  6 In the body of your report for this  7 case, you don't cite to any studies that comment  8 on talc and inflammation, correct?  9 MR. TISI: Objection.  10 Misstates. He says he relies on his own  11 studies.  12 MR. HEGARTY: Please, don't  13 answer for him, Chris.  14 MR. TISI: No, I'm not  15 answering for him.  16 MR. HEGARTY: Come on. It's  17 not a proper objection and you know it.  18 MR. TISI: It is. It is  19 because it's misleading.  20 BY MR. HEGARTY:  21 Q. You can answer, Doctor.  22 MR. TISI: To the extent you  23 rely on your prior studies, which are  24 clearly outlined in your report, you</p>	<p style="text-align: right;">Page 360</p> <p>1 body of your report any studies that talk about  2 talc and inflammation?  3 A. I have not, but I have done so in my  4 previous report, as I said before your discussion  5 with counsel here.  6 Q. As part of your work in preparing  7 your report, did you do a comprehensive medical  8 literature search with regard to inflammation and  9 ovarian cancer?  10 A. No, I didn't. Again, I didn't need  11 to do that in order to come to the conclusion that  12 there was a biologically plausible mechanism by  13 which ovarian -- by which talc could influence  14 ovarian cancer.  15 Q. Is it your opinion in this case that  16 inflammation is the cause of ovarian cancer?  17 MR. TISI: Objection.  18 THE WITNESS: I -- I cannot  19 state any one particular pathogenic  20 mechanism is responsible for the path --  21 for the carcinogenic process. There are  22 several that have been proposed.  23 BY MR. HEGARTY:  24 Q. Please turn to page 19 of your</p>
<p style="text-align: right;">Page 359</p> <p>1 clearly incorporate, you're entitled to  2 that. Word piece is not appropriate.  3 MR. HEGARTY: Chris, I think  4 I'm going -- we're going to have an issue  5 with the judge. We'll just swear you in.  6 You just gave him an answer to give back  7 to me.  8 MR. TISI: No, I didn't.  9 MR. HEGARTY: Yes, you did.  10 MR. TISI: It's so unfair what  11 you're doing.  12 MR. HEGARTY: Well --  13 MR. TISI: When he says --  14 when he says he --  15 MR. HEGARTY: -- we'll let the  16 judge decide if that was unfair.  17 MR. TISI: When he says --  18 when he says he incorporates by reference  19 his own studies and his own studies  20 discuss it.  21 MR. HEGARTY: We're not going  22 to reach an agreement on this.  23 BY MR. HEGARTY:  24 Q. Doctor, do you cite anywhere in the</p>	<p style="text-align: right;">Page 361</p> <p>1 report, if you're not there already.  2 A. I am there.  3 Q. In the upper part of that page of  4 your report, you make reference to a statement by  5 the American Statistical Association, correct?  6 A. Yes.  7 Q. And that statement you make is in  8 support of the statements you make in that  9 paragraph that:  10 "A consensus is slowly building  11 among scientists that statistical significant  12 testing has been a source of many errors in  13 interpretation, and should be avoided."  14 Correct?  15 A. That's correct.  16 MR. HEGARTY: I'm going to  17 mark as our next exhibit, Exhibit 25, a  18 document entitled "ASA President's Task  19 Force Statement on Statistical  20 Significance and Replicability."  21 (Document marked for  22 identification as Harlow Exhibit 25.)  23 BY MR. HEGARTY:  24 Q. Please excuse the highlighting.</p>

<p style="text-align: right;">Page 362</p> <p>1 They copied my highlighting when they weren't 2 supposed to. 3 A. Uh-huh. 4 Q. Have you read this before right now? 5 A. I don't believe I have since this 6 was not in the scientific literature, and my 7 reference is by Amrhein, Greenland, and McShane. 8 Q. I'm talking about the reference you 9 make on page 19 -- 10 A. I understand. 11 Q. -- of the American Statistical 12 Association. 13 A. I understand, and it comes from -- 14 oh. It is -- it is a quote that was stated in the 15 article by Amrhein. 16 One recent commentary in "Nature" 17 and endorsed by 800 signatories stated this. 18 Oh, and then you're talking about 19 the consensus statement from the American 20 Statistical Association above. 21 Q. Right. That's what I'm referring 22 to. 23 A. "A p-value, or statistical 24 significance, does not measure." Yes.</p>	<p style="text-align: right;">Page 364</p> <p>1 statistical inference that may be useful to the 2 scientific community." 3 Did I read that correctly? 4 A. Yes, you did. 5 Q. Do you disagree with that last 6 statement that I just read? 7 A. I've never disagreed that p-values 8 are not a tool in determining -- in determining a 9 strength of an association, but you don't need a 10 p-value. You can look at the confidence intervals 11 to determine whether or not the confidence 12 interval includes or doesn't include 1.0 and, by 13 definition, that is essentially showing what the 14 p-value might be. 15 Q. Please look at the very last 16 sentence on page 1. 17 A. Yes. 18 Q. It reads: 19 "P-values are valid statistical 20 measures that provide convenient conventions for 21 communicating the uncertainty inherited -- 22 inherent in quantitative results. Indeed, 23 p-values and significance tests are among the most 24 studied and best understood statistical procedures</p>
<p style="text-align: right;">Page 363</p> <p>1 Q. Please look at Exhibit Number 25. 2 A. I'm looking. 3 Q. It says in the first full 4 paragraph -- 5 A. On what page? 6 Q. First paragraph. 7 A. Yes. 8 Q. First page. 9 A. Yes. 10 Q. Second sentence. 11 "In 2019, the president of the 12 American Statistical Association established a 13 task force to address concerns a 2019 editorial in 14 'The American Statistician' (an ASA journal) might 15 be mistakenly interpreted as official ASA policy. 16 (The editorial recommended eliminating the use of 17 'p less than .05' and 'statistically significant' 18 in statistical analysis.) This document is the 19 statement of the task force, and the ASA invited 20 us to publicize it. Its purpose is two-fold: to 21 clarify that the use of p-values and significance 22 testing, properly applied and interpreted, are 23 important tools that should not be abandoned and 24 to briefly set out some principles of sound</p>	<p style="text-align: right;">Page 365</p> <p>1 in the statistics literature." 2 Do you agree with those two 3 statements? 4 A. Sure. 5 Q. Carrying on in that paragraph, it 6 goes on to say: 7 "They are important tools that have 8 advanced science through their proper 9 application." 10 Do you agree with that statement? 11 A. "Through their proper application," 12 yes. 13 Q. Please look at the very last line in 14 the middle of that page that begins "In summary." 15 MR. TISI: Feel free to take a 16 look at the document. 17 THE WITNESS: Yeah. I'm just 18 not seeing where it says "In summary." 19 BY MR. HEGARTY: 20 Q. Right in the middle. Right there. 21 MR. TISI: I know, but feel 22 free to look at it if you have not seen 23 it. 24 THE WITNESS: Oh, yeah, I can</p>

<p style="text-align: right;">Page 366</p> <p>1 see.</p> <p>2 MR. TISI: If you have not</p> <p>3 seen this recently, please take a look at</p> <p>4 it.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. It reads:</p> <p>7 "In summary, p-values and</p> <p>8 significance tests, when properly applied and</p> <p>9 interpreted, increase the rigor of the conclusions</p> <p>10 drawn from data. Analyzing data and summarizing</p> <p>11 results are often more complex than is sometimes</p> <p>12 popularly conveyed. Although all scientific</p> <p>13 methods have limitations, the proper application</p> <p>14 of statistical methods is essential for</p> <p>15 interpreting the results of data analyses and</p> <p>16 enhancing the replicability of scientific</p> <p>17 results."</p> <p>18 Do you agree with all those</p> <p>19 statements?</p> <p>20 A. I do, but that does not talk about</p> <p>21 the use of statistical significance for making</p> <p>22 inferences about causation. It is one of many</p> <p>23 tools that we use to assess the precision of risk</p> <p>24 estimates.</p>	<p style="text-align: right;">Page 368</p> <p>1 in front of me. But probably like 0.8 or 0.9 to</p> <p>2 about 1.3 or 1.4.</p> <p>3 If you assume that that is an</p> <p>4 attenuation of the true effect and that the</p> <p>5 multiple, multiple case-control studies have all</p> <p>6 shown an association of about 1.3, to me that</p> <p>7 seems fairly comparable.</p> <p>8 So that's the way I would interpret</p> <p>9 it, and that's the way both Dr. Rothman and I</p> <p>10 interpreted that, and we tried to explain that</p> <p>11 rationale.</p> <p>12 Q. We talked somewhat today about the</p> <p>13 O'Brien 2020 study, and you talk about it in your</p> <p>14 expert report, correct?</p> <p>15 A. That's correct.</p> <p>16 MR. HEGARTY: I've marked as</p> <p>17 Exhibit Number 26 the 2020 O'Brien study.</p> <p>18 (Document marked for</p> <p>19 identification as Harlow Exhibit 26.)</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. You have read that study; is that</p> <p>23 correct?</p> <p>24 A. Not only have I read it, I've</p>
<p style="text-align: right;">Page 367</p> <p>1 Q. You make the statement in your</p> <p>2 report that you found that there is reasonable</p> <p>3 consistency between case-control and cohort</p> <p>4 studies.</p> <p>5 What did you mean by "reasonable</p> <p>6 consistency"?</p> <p>7 A. Under the assumption that based on</p> <p>8 the limitations of the cohort study in terms of</p> <p>9 the way in which they assessed exposure, we can</p> <p>10 expect that those overall risk estimates are</p> <p>11 attenuated because of that.</p> <p>12 Thus, given that there is an</p> <p>13 attenuation of the cohort study estimates in the</p> <p>14 one cohort study I believe to be the best in terms</p> <p>15 of approximating the true risk, which is the</p> <p>16 Nurses' Health Study, I see that -- I see that the</p> <p>17 association on all not all that different.</p> <p>18 Even if you take the likely</p> <p>19 attenuated association of 1.09, which you continue</p> <p>20 to refer to as the overall association, even</p> <p>21 though in further analyses in that paper it's</p> <p>22 substantially higher, it's not unreasonable -- and</p> <p>23 you look at the confidence interval that's</p> <p>24 probably around -- I don't know. I don't have it</p>	<p style="text-align: right;">Page 369</p> <p>1 written a letter to the editor.</p> <p>2 Q. Which we'll talk about as well here</p> <p>3 in a moment.</p> <p>4 Please turn over to page 56 of this</p> <p>5 paper. Under the "Discussion" section.</p> <p>6 A. Uh-huh.</p> <p>7 Q. The very first line reads:</p> <p>8 "In this pooled of analysis of 4</p> <p>9 large U.S. cohorts, there was no statistically</p> <p>10 significant association between self-reported use</p> <p>11 of powder in the genital area and risk of ovarian</p> <p>12 cancer."</p> <p>13 That's a correct statement, true?</p> <p>14 A. Well, I believe that I took issue</p> <p>15 with that particular statement because other</p> <p>16 findings in this particular paper showed a</p> <p>17 different association in those with patent genital</p> <p>18 tracts.</p> <p>19 Q. The next line says:</p> <p>20 "There were no clear dose-response</p> <p>21 transfer for duration and frequency of powder use</p> <p>22 in the genital area in relation to ovarian cancer</p> <p>23 risk."</p> <p>24 Those are -- those are also true</p>

<p style="text-align: right;">Page 370</p> <p>1 statements, correct?</p> <p>2 A. Those -- that's what they said, but,</p> <p>3 again, as I pointed out in the report and even in</p> <p>4 my letter to the editor, exposure assessment in</p> <p>5 two of these three -- I mean, really all of them,</p> <p>6 but particularly in two of the three -- were not</p> <p>7 -- were -- were incomplete in terms of being able</p> <p>8 to truly obtain the kind of exposure assessment</p> <p>9 that we're actually able to do in case-control</p> <p>10 studies.</p> <p>11 And the issue -- well, I'll just</p> <p>12 stop there. Go ahead and ask another question.</p> <p>13 Q. As you mentioned just a moment ago,</p> <p>14 you do make reference to the study's findings with</p> <p>15 regard to the data as to women with patent genital</p> <p>16 tracts, correct?</p> <p>17 A. Yes.</p> <p>18 Q. As the authors note, though --</p> <p>19 A. Uh-huh.</p> <p>20 Q. -- they found no statistical</p> <p>21 difference between -- in the data between women</p> <p>22 with patent tubes and women who did not have</p> <p>23 patent tubes, correct?</p> <p>24 A. And where do they specifically say</p>	<p style="text-align: right;">Page 372</p> <p>1 a patent open genital tract are going to be at</p> <p>2 lower risk if not null risk for -- for this</p> <p>3 association.</p> <p>4 Q. Dr. Harlow, statistically, there was</p> <p>5 no difference between women with patent and</p> <p>6 without patent tubes, correct?</p> <p>7 MR. TISI: Objection. Asked</p> <p>8 and answered.</p> <p>9 THE WITNESS: Well, no. I'm</p> <p>10 sorry.</p> <p>11 MR. TISI: You got to let me</p> <p>12 object.</p> <p>13 THE WITNESS: Sorry.</p> <p>14 MR. TISI: Objection. Asked</p> <p>15 and answered.</p> <p>16 You may answer.</p> <p>17 THE WITNESS: Sorry.</p> <p>18 MR. TISI: No, that's okay.</p> <p>19 THE WITNESS: Just because</p> <p>20 there the difference between 1.0 -- 1.0</p> <p>21 with a confidence interval with a -- with</p> <p>22 a confidence interval of .86 to 1.15,</p> <p>23 which is almost directly, directly,</p> <p>24 estimated as null with a hazard of 0.99,</p>
<p style="text-align: right;">Page 371</p> <p>1 that?</p> <p>2 Q. Please look at the abstract.</p> <p>3 A. Well, I'm looking at on page 54</p> <p>4 where they say in the second column:</p> <p>5 "When restricted to women with</p> <p>6 patent reproductive tracts at baseline, the hazard</p> <p>7 ratio was 1.13 and the estimated</p> <p>8 covariate-adjusted risk difference was 0.15.</p> <p>9 Among women without patent reproductive tracts,</p> <p>10 the estimated hazard ratio was 0.99."</p> <p>11 Q. Then they go on to say:</p> <p>12 "And the P value for heterogeneity</p> <p>13 comparing the results for women with patency</p> <p>14 versus without was .15."</p> <p>15 Correct?</p> <p>16 A. That's what they say, but one</p> <p>17 doesn't need to do a statistical test of</p> <p>18 differences to recognize that the association</p> <p>19 seems to be much strongly observed in those with a</p> <p>20 patent -- patent tract.</p> <p>21 And as I believe Dr. Rothman and</p> <p>22 Murray and I commented in our letter to the editor</p> <p>23 that it's -- it's -- you don't need to do a</p> <p>24 statistical test to show that women who don't have</p>	<p style="text-align: right;">Page 373</p> <p>1 to have to say that that is statistically</p> <p>2 different from a hazard ratio of 1.13</p> <p>3 with a confidence interval of 1.01 to</p> <p>4 1.26 would -- does it make sense to then</p> <p>5 say, oh, because they're not</p> <p>6 statistically different, then we don't</p> <p>7 believe -- then we should just ignore</p> <p>8 that association that we see in women</p> <p>9 with patent genital tracts.</p> <p>10 It is ludicrous to apply a</p> <p>11 statistical test in this situation to</p> <p>12 diminish or ignore an association, in my</p> <p>13 view.</p> <p>14 MR. HEGARTY: Let me show you</p> <p>15 what I've marked as Exhibit Number 27.</p> <p>16 (Document marked for</p> <p>17 identification as Harlow Exhibit 27.)</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Exhibit Number 27 is an editorial --</p> <p>20 A. Yes.</p> <p>21 Q. -- that was written --</p> <p>22 A. Yeah.</p> <p>23 Q. -- with regard to the 2020 O'Brien</p> <p>24 study by Drs. Gossett and del Carmen.</p>

<p style="text-align: right;">Page 374</p> <p>1 Have you read this before today?</p> <p>2 A. I have.</p> <p>3 Q. Do you know either of these two</p> <p>4 doctors?</p> <p>5 A. I don't know them.</p> <p>6 Q. Please turn over to page 30.</p> <p>7 A. Uh-huh.</p> <p>8 Q. Towards the bottom of the left-hand</p> <p>9 column.</p> <p>10 A. Uh-huh.</p> <p>11 Q. Beginning with "The fact that."</p> <p>12 Do you see where I'm reading?</p> <p>13 A. Is it in the left-hand column?</p> <p>14 Q. Left-hand column.</p> <p>15 A. Hold on.</p> <p>16 Q. Right here. Very bottom paragraph.</p> <p>17 A. In fact.</p> <p>18 Q. "The fact that." That's the</p> <p>19 beginning of the sentence.</p> <p>20 A. Oh, got it. Thank you.</p> <p>21 Q. It reads:</p> <p>22 "The fact that there was -- there</p> <p>23 are no significant differences in the HRs in the</p> <p>24 patent (HR, 1.13 [95% confidence interval, 1.01 to</p>	<p style="text-align: right;">Page 376</p> <p>1 Q. She's talking about you, right?</p> <p>2 MR. TISI: Objection. Come</p> <p>3 on.</p> <p>4 THE WITNESS: What do you</p> <p>5 mean she's talking about me?</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. Well, she --</p> <p>8 MR. TISI: Are you suggesting</p> <p>9 with all his background? Honestly, that</p> <p>10 is insulting.</p> <p>11 MR. HEGARTY: Please. Please.</p> <p>12 MR. TISI: Do not insult my</p> <p>13 witness ever.</p> <p>14 MR. HEGARTY: Please. Chris,</p> <p>15 Make an objection. Make an objection.</p> <p>16 MR. TISI: You are suggesting</p> <p>17 he's epidemiologically unsophisticated?</p> <p>18 That's beneath you.</p> <p>19 MR. HEGARTY: I asked if she</p> <p>20 was talking about you.</p> <p>21 MR. TISI: Oh, you think so?</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. You can answer.</p> <p>24 A. Well, first of all --</p>
<p style="text-align: right;">Page 375</p> <p>1 1.26]) and nonpatent subgroups (HR, .99 [95%</p> <p>2 confidence interval, 0.86 to 1.15]; P value for</p> <p>3 heterogeneity comparing these subgroups of .15)</p> <p>4 confirms the overall conclusion that there is no</p> <p>5 demonstrable statistically significant association</p> <p>6 between use of powder in the genital area and</p> <p>7 ovarian cancer risk."</p> <p>8 First of all, did I read that</p> <p>9 correctly?</p> <p>10 A. You read what was written there,</p> <p>11 yes, correctly.</p> <p>12 Q. Carrying over to the next paragraph</p> <p>13 from the bottom.</p> <p>14 A. Yeah.</p> <p>15 Q. "The subgroup analysis suggesting</p> <p>16 that women with intact reproductive tracts who</p> <p>17 used powder in the perineal area developed ovarian</p> <p>18 cancer more frequently than nonusers is below the</p> <p>19 effect size that epidemiologists generally</p> <p>20 consider important and should not be selectively</p> <p>21 highlighted by the statistically unsophisticated</p> <p>22 reader as evidence of a relationship."</p> <p>23 Did I read that correctly?</p> <p>24 A. You did read it correctly.</p>	<p style="text-align: right;">Page 377</p> <p>1 MR. TISI: Ask her about the</p> <p>2 statement.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. You can answer the question.</p> <p>5 MR. TISI: Ask her about --</p> <p>6 ask him about the statement.</p> <p>7 MR. HEGARTY: Are you</p> <p>8 instructing him not to answer my</p> <p>9 question?</p> <p>10 MR. TISI: I'm telling you to</p> <p>11 ask a nonridiculous question.</p> <p>12 MR. HEGARTY: I'm not going to</p> <p>13 listen to what you tell me, Chris.</p> <p>14 Please be quiet and let him answer the</p> <p>15 question.</p> <p>16 MR. TISI: Don't ever do that</p> <p>17 to one of my witnesses again.</p> <p>18 MR. HEGARTY: I'm not</p> <p>19 listening to you what you say. My</p> <p>20 question is appropriate.</p> <p>21 MR. TISI: You better listen.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Was that statement talking about</p> <p>24 your -- what you just told me about why you reject</p>



<p style="text-align: right;">Page 378</p> <p>1 statistical significance between the patent and 2 nonpatent groups in this study? 3 A. First of all, they couldn't be 4 talking about me because I wrote my letter to the 5 editor about this after this commentary had been 6 written. So I don't know how they could possibly 7 be directing this comment to me. 8 Q. Okay. Is this not addressing the 9 issue you and I have been talking about about 10 statistical significance between the patent and 11 nonpatent tubes to patients? 12 A. It is, and I don't know who this 13 person is, but I don't see that they have a 14 doctoral degree in epidemiology. And I don't 15 believe that that kind -- that to me is what the 16 American Statistical Association was saying in 17 terms of inappropriately using statistical 18 significance to make clinically relevant 19 decisions. 20 So in my field, we would not make 21 that kind of a statement that would, in my view, 22 minimize a potential risk of something that has 23 been shown to possibly impact 10 percent of the 24 incidence of ovarian cancer.</p>	<p style="text-align: right;">Page 380</p> <p>1 Who is the primary, if there was 2 one, author of this document, of this letter to 3 the editor? 4 A. Well, I was the first author, but I 5 -- it was a -- somebody had to be first. It was a 6 collaboration between the three of us. 7 I was the one who initiated this 8 collaboration in response to this. 9 Q. At the time that you wrote this 10 letter to the editor -- 11 A. Yes. 12 Q. -- you had been serving as a 13 consultant to plaintiffs' lawyers in cases 14 involving talcum powder use and ovarian cancer, 15 correct? 16 MR. TISI: Objection. 17 THE WITNESS: No, that's not 18 true. 19 I told you, I believe, earlier 20 that I had stopped doing that as of 2017. 21 This was written in 2020. 22 BY MR. HEGARTY: 23 Q. Please look at the conflict of 24 interest disclosure --</p>
<p style="text-align: right;">Page 379</p> <p>1 So I'm sorry. That's -- that's an 2 inappropriate -- inappropriate comment. 3 MR. HEGARTY: You mentioned 4 your commentary and I marked your 5 commentary as Exhibit Number 28. 6 (Document marked for 7 identification as Harlow Exhibit 28.) 8 THE WITNESS: My letter to 9 the editor? 10 BY MR. HEGARTY: 11 Q. Sorry. I misspoke. 12 A. No worries. 13 Q. Your letter to the editor, which 14 happens to be under the "Comment &amp; Response" 15 section, correct? 16 A. Yes. 17 Q. With regard to the letter to the 18 editor that we're looking at in Exhibit 28 -- 19 A. Yes. 20 Q. -- your letter to the editor begins 21 over on page 2096, correct? 22 A. Yes, that's correct. 23 Q. The letter to the editor is from 24 three authors.</p>	<p style="text-align: right;">Page 381</p> <p>1 A. Yes. 2 Q. -- in this document. 3 A. Yes. 4 Q. It reads: 5 "Dr. Harlow reported publishing 6 research and serving as a consultant on the topic 7 of talc and ovarian cancer risk." 8 Did I read that correctly? 9 A. That's correct, but I was not at the 10 time serving as a consultant. I was -- I was 11 doing the appropriate thing and letting the 12 readership know that I had been a consultant at 13 some point, but I was not when I wrote this letter 14 to the editor. 15 Q. Was your intent by that statement to 16 refer back to the consulting you and I talked 17 about with regard to the Chakalos case and other 18 cases? 19 A. My intent was to be forthcoming in 20 letting the readership know that I had received 21 some consulting arrangements in the past around 22 this. 23 Q. You did not report to the reader on 24 whose side you had consulted --</p>

<p style="text-align: right;">Page 382</p> <p>1 A. I did --</p> <p>2 Q. -- with regard to talc and ovarian</p> <p>3 cancer, correct?</p> <p>4 A. I did not.</p> <p>5 Q. Do you think it's important -- let</p> <p>6 me ask a different way.</p> <p>7 Do you not think it's important for</p> <p>8 the reader to know whether you had been a</p> <p>9 consultant for plaintiffs' lawyers who are</p> <p>10 bringing lawsuits involving talcum powder use</p> <p>11 versus Johnson &amp; Johnson who's defending lawsuits</p> <p>12 involving talcum powder use?</p> <p>13 A. I was not an expert. I was not</p> <p>14 doing any expert testimony.</p> <p>15 I was merely being a consultant and</p> <p>16 evaluating scientific literature. It had no</p> <p>17 bearing on my interpretation.</p> <p>18 And all three of my coauthors and I</p> <p>19 have -- again, I had no idea what Dr. Rothman had</p> <p>20 or had not done. When I wrote this, I did not</p> <p>21 know about his report in 2000. And to my</p> <p>22 knowledge, Dr. Murray has not been involved in any</p> <p>23 of this.</p> <p>24 This was a collaborative letter that</p>	<p style="text-align: right;">Page 384</p> <p>1 consultant with regard to talc and ovarian cancer?</p> <p>2 MR. TISI: Objection. Asked</p> <p>3 and answered.</p> <p>4 THE WITNESS: I didn't feel</p> <p>5 it had any influence or bearing on my --</p> <p>6 on my conclusions here and, as I just</p> <p>7 indicated before, this is a joint letter</p> <p>8 between the three of us. And even if I</p> <p>9 was trying to bias in one direction, it</p> <p>10 would never have been approved by my</p> <p>11 coauthors.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. If you were to write this letter</p> <p>14 today, would you identify in your conflict of</p> <p>15 interest disclosure that you're a</p> <p>16 consultant/expert testifying for plaintiffs in</p> <p>17 cases involving talcum powder use and ovarian</p> <p>18 cancer?</p> <p>19 MR. TISI: Objection.</p> <p>20 THE WITNESS: May I answer</p> <p>21 the question?</p> <p>22 MR. TISI: Sure.</p> <p>23 THE WITNESS: Yes, I would.</p> <p>24 Yes, I would. I'm not sure I would be</p>
<p style="text-align: right;">Page 383</p> <p>1 we wrote, and I could never have influenced my</p> <p>2 colleagues one way or another because of any kind</p> <p>3 of past consulting that I've done.</p> <p>4 Q. You don't disclose a prior</p> <p>5 relationship in a conflict of interest disclosure</p> <p>6 only if you believe it is biasing your statements</p> <p>7 or your opinions that you are writing, correct?</p> <p>8 MR. TISI: Objection.</p> <p>9 THE WITNESS: I'm sorry. Can</p> <p>10 you repeat that question?</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. Sure.</p> <p>13 You don't only identify a conflict</p> <p>14 of interest when you believe you are presenting</p> <p>15 biased statements in a publication, correct?</p> <p>16 A. I -- anytime I would be -- would</p> <p>17 write anything around the talc and ovarian cancer</p> <p>18 beyond what I had already published, knowing that</p> <p>19 I had spent a period of time as a consultant, it</p> <p>20 would have been inappropriate for me not to have</p> <p>21 indicated that disclosure, and so that's what I</p> <p>22 did here.</p> <p>23 Q. Don't you think the reader was</p> <p>24 entitled to know on whose side you had been a</p>	<p style="text-align: right;">Page 385</p> <p>1 comfortable in a position doing that</p> <p>2 simply because of the situation that I'm</p> <p>3 in right now.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Please look at Drs. O'Brien,</p> <p>6 Sandler, and Wentzensen's response letter at the</p> <p>7 bottom of page 2096 to 2097.</p> <p>8 You've read that before today,</p> <p>9 correct?</p> <p>10 A. Oh. Oh, Dr. O'Brien's response.</p> <p>11 Q. Yes, or reply.</p> <p>12 A. Yes. Yes, yes, yes. I'm sorry.</p> <p>13 Yes. Uh-huh.</p> <p>14 Q. Please look at the bottom of page</p> <p>15 2096 in the right-hand column, second paragraph.</p> <p>16 Dr. O'Brien and her coauthors write:</p> <p>17 "Conversely, empirical evidence</p> <p>18 supports that recall bias is present in</p> <p>19 retrospective studies."</p> <p>20 That's what Dr. O'Brien wrote,</p> <p>21 correct?</p> <p>22 A. This was, again, not in response to</p> <p>23 my letter. This was in response to Dr. Cramer's</p> <p>24 letter.</p>

<p style="text-align: right;">Page 386</p> <p>1 Q. But without regard to who she's</p> <p>2 responding to, that's what she wrote, correct?</p> <p>3 A. She did write that.</p> <p>4 But as you note in my report, there</p> <p>5 are a number of -- of citations where I indicated</p> <p>6 that recall bias has minimal to little impact on</p> <p>7 estimates.</p> <p>8 Q. So you disagree with that statement?</p> <p>9 A. I don't disagree that there can be</p> <p>10 recall bias in retrospective studies. I believe</p> <p>11 I've been very clear that recall bias in those who</p> <p>12 are at the highest level of exposure is unlikely</p> <p>13 to explain the associations that we've observed.</p> <p>14 Q. The next statement by Dr. O'Brien</p> <p>15 and others says:</p> <p>16 "While true never users are unlikely</p> <p>17 to report daily use, some users may fail to report</p> <p>18 use and others may misreport frequency and</p> <p>19 duration of use or type of product used. If</p> <p>20 misclassification is differential by case status,</p> <p>21 it could influence effect estimates in</p> <p>22 case-control studies."</p> <p>23 Do you agree with those statements?</p> <p>24 A. Yes, but it could influence in</p>	<p style="text-align: right;">Page 388</p> <p>1 intact reproductive tracts, should not be</p> <p>2 discounted because of lack of statistical</p> <p>3 significance. For all estimates we reported 95</p> <p>4 percent confidence intervals.</p> <p>5 So do I believe that this is</p> <p>6 important addition to the literature? Yes, I</p> <p>7 absolutely do, when considering the limitations</p> <p>8 related to these cohort studies.</p> <p>9 I'm not suggesting this is not an</p> <p>10 important contribution. I'm suggesting that, in</p> <p>11 our view, given the attenuation that is likely to</p> <p>12 be occurring for many of the reasons that we</p> <p>13 report in the letter, that we report in our</p> <p>14 report, make this an important contribution and to</p> <p>15 me validates the consistency of the findings that</p> <p>16 we see in case-control studies.</p> <p>17 Q. Dr. O'Brien in her reply doesn't</p> <p>18 retract or withdraw the 2020 O'Brien paper or any</p> <p>19 statements in it, correct?</p> <p>20 A. No. She merely agrees with our</p> <p>21 interpretation.</p> <p>22 Q. She agrees with what she says she</p> <p>23 agrees with in her reply, correct?</p> <p>24 A. That's right, but I believe there's</p>
<p style="text-align: right;">Page 387</p> <p>1 either direction. It doesn't necessarily</p> <p>2 influence in one direction or the other.</p> <p>3 Q. Please look at the very last</p> <p>4 paragraph on the next page of Dr. O'Brien and</p> <p>5 others' response. Please tell me when you can --</p> <p>6 where you're at. The paragraph that begins "We</p> <p>7 agree."</p> <p>8 A. Yes, I'm here.</p> <p>9 Q. In the middle of that paragraph, the</p> <p>10 authors write:</p> <p>11 "However, because of the rarity of</p> <p>12 ovarian cancer and the risk of recall bias in</p> <p>13 retrospective studies, we think that despite the</p> <p>14 limitations, the prospective cohorts included in</p> <p>15 the analysis offered -- included in -- included in</p> <p>16 the analysis offered important new data for</p> <p>17 addressing this question."</p> <p>18 Do you agree with that statement?</p> <p>19 A. Well, yes, because I had</p> <p>20 specifically stated that -- that I -- we felt that</p> <p>21 the association was -- was, in fact, there. And</p> <p>22 they specifically said that they completely agree</p> <p>23 with me and colleagues that our results,</p> <p>24 particularly the analyses limited to women with</p>	<p style="text-align: right;">Page 389</p> <p>1 more than one place where she agrees.</p> <p>2 Q. It says what it says, right?</p> <p>3 A. Yeah, yeah. It says what it says.</p> <p>4 Q. All right. Thank you.</p> <p>5 A. Yeah.</p> <p>6 Q. You can put that aside.</p> <p>7 A. Okay.</p> <p>8 Q. You mentioned a moment ago a</p> <p>9 reference to this 10 percent number that you</p> <p>10 reported in your 1992 study, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Is it your opinion that 10 percent</p> <p>13 of ovarian cancers diagnosed in 2024 are caused by</p> <p>14 talcum powder?</p> <p>15 A. At the time I wrote that, it was</p> <p>16 based on the risk estimates that we saw in 1992,</p> <p>17 and at that point, that was my estimate of the</p> <p>18 potential proportion of the incidence that could</p> <p>19 be explained by talc exposure.</p> <p>20 Q. My question --</p> <p>21 A. I don't know what talc -- what's</p> <p>22 happening now with respect to talc exposure. I</p> <p>23 suspect that given that they have taken the</p> <p>24 product off the market and there have been a lot</p>

<p style="text-align: right;">Page 390</p> <p>1 of media around this in the news that perhaps the 2 prevalence of the exposure has decreased recently. 3 I just don't know. 4 Q. My question is to find out if you 5 have this opinion. 6 And is it your opinion that sitting 7 here today that 10 percent of ovarian cancer 8 diagnosed this year in 2024 will have been caused 9 by genital use of talcum powder? 10 A. Given that the most recent studies 11 that were done in 2016, eight years ago, found 12 similar risks as we found in 1992, and given that 13 there is a certain period of time that exposure 14 needs to occur in order to likely induce a 15 carcinogenic process, I would say that it's quite 16 likely that 10 percent of the incidence of ovarian 17 cancer today could be attributable to talc 18 exposure from the past. 19 Q. So is it your opinion that with 20 regard to 2000 women or 10 percent of women 21 diagnosed in 2024 with ovarian cancer, that they 22 never would have developed ovarian cancer if they 23 had not used talcum powder? 24 A. I can't -- I can't say that, but</p>	<p style="text-align: right;">Page 392</p> <p>1 association, other than the fact that McDonald had 2 tried to do that in a very small sample. 3 Q. Can you cite for me any study 4 reporting talc in the presence of inflammation in 5 the ovary before ovarian cancer has been 6 diagnosed? 7 A. I don't know of any studies like 8 that. 9 Q. Can you cite to any studies showing 10 an association between talc in the ovaries and 11 ovarian cancer risk, that is, having an increase 12 in risk if there's a prior finding of talc in the 13 ovaries? 14 A. I don't believe that kind of a study 15 has been done or really could be done in women who 16 don't have ovarian cancer. I don't know how you 17 would be able to biopsy essentially the tissue in 18 order to make that determination in healthy women. 19 Q. With regard to what you've generated 20 in this case as part of your work, we've talked 21 about the materials you brought with you. We 22 talked about your report. 23 Have you otherwise provided to the 24 attorneys representing plaintiffs in this case all</p>
<p style="text-align: right;">Page 391</p> <p>1 even if half of them didn't, being able to prevent 2 a thousand cases of ovarian cancer a year is a 3 huge public health intervention. 4 MR. HEGARTY: Let's go off the 5 record real quick. 6 (Recess: 5:19 p.m. - 7 5:33 p.m.) 8 MR. HEGARTY: We are back on 9 the record. 10 BY MR. HEGARTY: 11 Q. Dr. Harlow, I might jump around a 12 little bit on subject areas with my remaining 13 time. 14 We talked earlier about the findings 15 from McDonald about talc in the ovaries of the 16 women studied both in the cases and the controls. 17 Can you cite for me any studies 18 showing an increase in risk of ovarian cancer in 19 women who have talc in their ovaries? 20 A. I don't believe there's any studies 21 that have been done that would have identified 22 women with ovarian cancer and talc in their 23 ovaries compared to women with ovarian cancer and 24 not talc in their ovaries and looking at the</p>	<p style="text-align: right;">Page 393</p> <p>1 the materials you reviewed and all the work 2 product you've generated as part of your work on 3 this case? 4 A. I believe so. 5 Again, as of this point, yes, but I 6 don't know what will become available in the 7 future. 8 Q. All I'm asking you about is what you 9 can testify to today. 10 A. Yeah. 11 Q. Have you provided to the lawyers 12 representing the plaintiffs in this case all the 13 materials you've reviewed and generated as part of 14 your work on this case? 15 A. Yes. 16 Q. And do you know if Dr. Rothman ever 17 provided all the materials he worked on or 18 reviewed as part of his work on this case? 19 A. I don't -- I don't know what he did 20 in prior to him inviting me to work with him. So 21 I don't know what he had done and what might have 22 been provided. And I don't know believe there was 23 anything that he did while we were working 24 together that would have been independent of my --</p>

<p style="text-align: right;">Page 394</p> <p>1 my work.</p> <p>2 Q. As part of your work in this case or</p> <p>3 otherwise, have you ever reviewed what your</p> <p>4 university, Boston University, says about ovarian</p> <p>5 cancer risk factors?</p> <p>6 A. No.</p> <p>7 Q. Have you ever reviewed what Dana</p> <p>8 Farber says about ovarian cancer risk factors?</p> <p>9 A. No.</p> <p>10 Q. I'll represent to you that those</p> <p>11 websites, that the websites for those two</p> <p>12 facilities don't list talc as a risk factor for</p> <p>13 ovarian cancer.</p> <p>14 Do you have a response to that?</p> <p>15 MR. TISI: Objection. Vague</p> <p>16 and ambiguous and unanswerable but...</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. If you can answer.</p> <p>19 MR. TISI: You can answer if</p> <p>20 you even understand the question. I'm</p> <p>21 not sure I do.</p> <p>22 THE WITNESS: No, I understand</p> <p>23 the question, and I am sure they may be</p> <p>24 concerned, given the known litigation</p>	<p style="text-align: right;">Page 396</p> <p>1 A. I haven't.</p> <p>2 Q. What information do you have as far</p> <p>3 as whether these groups on their websites do or do</p> <p>4 not list talc as a risk factor for ovarian cancer?</p> <p>5 A. I would have to go and look on the</p> <p>6 website.</p> <p>7 Q. Do you have any comment as to those</p> <p>8 groups to the extent they don't list talc as a</p> <p>9 risk factor on their websites?</p> <p>10 MR. TISI: Objection. Vague.</p> <p>11 Ask him to speculate.</p> <p>12 Go ahead.</p> <p>13 THE WITNESS: I think if they</p> <p>14 don't list it, that it would be</p> <p>15 appropriate for them to -- to list it</p> <p>16 as -- as a potential risk factor that</p> <p>17 perhaps may not be advisable to be used.</p> <p>18 That would be my recommendation.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. You have not personally contacted</p> <p>21 SGO --</p> <p>22 A. No.</p> <p>23 Q. -- CDC or ACOG, correct?</p> <p>24 A. No.</p>
<p style="text-align: right;">Page 395</p> <p>1 that's going on, for them to come forward</p> <p>2 and put that kind of information on their</p> <p>3 external-facing page.</p> <p>4 That would be my guess. I</p> <p>5 have no other -- I have no known</p> <p>6 knowledge as to why they do or do not put</p> <p>7 that kind of information on their web --</p> <p>8 on their website.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Have you reviewed as part of your</p> <p>11 work in this case the list of risk factors</p> <p>12 reported by the Society of Gynecologic Oncology,</p> <p>13 the SGAO, the CDC?</p> <p>14 A. SGO.</p> <p>15 Q. SGO. Thank you.</p> <p>16 The SGO, the CDC, and ACOG?</p> <p>17 A. I am aware that they either do not</p> <p>18 indicate it as a risk factor or have indicated</p> <p>19 that it is unclear whether it is a risk factor or</p> <p>20 not. They may even have said it's not. I don't</p> <p>21 know.</p> <p>22 Q. Have you reviewed --</p> <p>23 A. I haven't.</p> <p>24 Q. -- the list and the risk factors?</p>	<p style="text-align: right;">Page 397</p> <p>1 Q. You make a reference in your report</p> <p>2 to a study by Taher, correct?</p> <p>3 A. T-a-h-e-r. Yes.</p> <p>4 Q. Please look at the end of your</p> <p>5 report the list of citations, and to what Taher</p> <p>6 study do you make reference to?</p> <p>7 A. Well, let me pull out the Taher</p> <p>8 study. It's right here.</p> <p>9 Q. No, I need you to look at your</p> <p>10 report and tell me what you specifically refer to</p> <p>11 at the back.</p> <p>12 A. Okay.</p> <p>13 Q. I want to make sure we start on the</p> <p>14 same page.</p> <p>15 A. I understand.</p> <p>16 MR. TISI: Is there only one?</p> <p>17 THE WITNESS: I don't know.</p> <p>18 MR. HEGARTY: That's what</p> <p>19 we're trying to find out.</p> <p>20 MR. TISI: Okay.</p> <p>21 THE WITNESS: Taher is -- is</p> <p>22 cited from the 2020 article. "Data on</p> <p>23 systematic review of meta-analysis of</p> <p>24 epidemiologic evidence."</p>



<p style="text-align: right;">Page 398</p> <p>1 MR. HEGARTY: And I'll mark as</p> <p>2 Exhibit 29 that 2020 article.</p> <p>3 (Document marked for</p> <p>4 identification as Harlow Exhibit 29.)</p> <p>5 THE WITNESS: Uh-huh.</p> <p>6 MR. HEGARTY: I'll also mark</p> <p>7 as Exhibit Number 30 the Taher 2019</p> <p>8 article.</p> <p>9 (Document marked for</p> <p>10 identification as Harlow Exhibit 30.)</p> <p>11 BY MR. HEGARTY:</p> <p>12 Q. My question is: When you talked</p> <p>13 about Taher in your report, were you intending to</p> <p>14 refer to the 2020 article or the 2019 article?</p> <p>15 A. Yeah, this is -- I believe it's the</p> <p>16 same data, but I probably was reviewing the</p> <p>17 critical -- it was -- it was this one, yeah. The</p> <p>18 critical -- the "Critical review."</p> <p>19 I wonder if I might have cited it</p> <p>20 wrong.</p> <p>21 Q. That was my question.</p> <p>22 A. Yeah.</p> <p>23 Q. When you make reference to Taher</p> <p>24 over on page 13 of your report --</p>	<p style="text-align: right;">Page 400</p> <p>1 when you are there.</p> <p>2 A. Uh-huh. I am there.</p> <p>3 Q. At the end of the first paragraph of</p> <p>4 the "Conclusion" section, the authors write:</p> <p>5 "Consistent with a previous</p> <p>6 evaluation by the IARC in 2010, the present</p> <p>7 evaluation of all currently available relevant</p> <p>8 data indicates that perineal exposure to talc</p> <p>9 powder is a possible cause of ovarian cancer in</p> <p>10 humans."</p> <p>11 Do you see where I'm reading?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Do you agree with that statement?</p> <p>14 A. Yes.</p> <p>15 Q. Please turn next in this paper over</p> <p>16 to page 96. Just above the "Discussion" section.</p> <p>17 A. Yes.</p> <p>18 Q. The paragraph just before the</p> <p>19 "Discussion" section reads:</p> <p>20 "Overall, the graphical results</p> <p>21 shown in this Figure 3 suggests a possible</p> <p>22 increasing trend in ovarian cancer risk with</p> <p>23 increasing cumulative exposure to talc; however,</p> <p>24 there is also a high degree of uncertainty</p>
<p style="text-align: right;">Page 399</p> <p>1 A. Yep.</p> <p>2 Q. -- carrying over to page 14, did you</p> <p>3 intend to actually cite Exhibit 30, which is the</p> <p>4 "Critical review," but instead you cited Exhibit</p> <p>5 29, the "Data on systematic review"?</p> <p>6 A. (Reviews document.)</p> <p>7 It looks like it's the 24</p> <p>8 case-control studies, and that would have been the</p> <p>9 article. So it was -- it was the critical</p> <p>10 evaluation paper.</p> <p>11 Q. So the citation in your report</p> <p>12 should be to Exhibit Number 30 instead of Exhibit</p> <p>13 Number 29?</p> <p>14 A. That's correct, and, in fact, the</p> <p>15 odds ratio that I present in my report is the one</p> <p>16 from 2019, the 1.28 in the abstract. Sorry.</p> <p>17 Q. Please note at Exhibit Number 30,</p> <p>18 the systematic review article.</p> <p>19 A. The Taher article?</p> <p>20 Q. The Taher article.</p> <p>21 A. Yes.</p> <p>22 Q. And turn over to page 99.</p> <p>23 Please look at the "Conclusion"</p> <p>24 section and tell me when you get there. Tell me</p>	<p style="text-align: right;">Page 401</p> <p>1 surrounding many of the individual risk</p> <p>2 estimates."</p> <p>3 Do you agree with that statement?</p> <p>4 MR. TISI: Objection.</p> <p>5 THE WITNESS: Well, as I look</p> <p>6 at the figure that they're referring to,</p> <p>7 all but two of the point estimates are</p> <p>8 above 1 from what I can see, maybe three,</p> <p>9 which is why they have a 1.28 with a very</p> <p>10 narrow confidence interval -- this is 24</p> <p>11 studies -- from 1.20 to 1.37.</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. So going back to my question: Do</p> <p>14 you agree with the way they characterize their</p> <p>15 data as I read to you in that sentence?</p> <p>16 A. Yeah. Where was that sentence</p> <p>17 again? Sorry.</p> <p>18 Q. It's in the -- it's in the paragraph</p> <p>19 above "Discussion."</p> <p>20 A. Right. Paragraph above</p> <p>21 "Discussion."</p> <p>22 (Reviews document.)</p> <p>23 Well, that's -- that's -- that's why</p> <p>24 doing this type of a meta-analysis of 24 studies</p>

<p style="text-align: right;">Page 402</p> <p>1 allows us to have better precision in the risk.  2 So any one particular study is going to not have  3 the precision that we would gain by being able to  4 meta-analyze 24 of them together.  5 So when they say "there is also a  6 high degree of uncertainty surrounding many of the  7 individual risk estimates," that's the whole  8 reason why we do meta-analyses like this,  9 especially in the context of something like this  10 association which is around 1.3 and you have  11 variability around that.  12 Q. If there is systematic error in a  13 case-control or cohort study -- and let me expand  14 that.  15 If there are systematic errors in  16 cases in control studies that you combine in a  17 meta-analysis, combining them in a meta-analysis  18 will not correct the systematic errors, correct?  19 MR. TISI: Objection.  20 THE WITNESS: Well, I don't  21 know that -- I don't believe they said  22 system -- I don't believe he said  23 systematic -- systematic error.  24 What did you say it was? I'm</p>	<p style="text-align: right;">Page 404</p> <p>1 meta-analysis will not correct the systematic  2 error?  3 A. That is correct. You would have to  4 make the assumption that the dozens of  5 case-control studies that are all showing a risk  6 of about 1.3 to 1.5 -- well, as I say, 1.0 to  7 1.8 -- would systematically all be having an error  8 in the same direction and that's highly unlikely.  9 Q. In that same part of the Taher  10 paper, after the statement I read to you, the  11 authors go on to say:  12 "A formal statistical test for trend  13 was not attempted because of the high degree of  14 heterogeneity among studies noted previously in  15 our meta-analysis discussed in Section 3.4."  16 Is that saying that there was --  17 that they did not do a formal statistical test for  18 trend, in your opinion, because of the differences  19 across the studies that was reflected in their  20 test for heterogeneity?  21 A. I'm not sure what they're referring  22 to in a statistical test of trend because usually  23 a statistical test of trend is looking within a  24 particular study, or if you're pooling studies,</p>
<p style="text-align: right;">Page 403</p> <p>1 sorry. That term you used.  2 BY MR. HEGARTY:  3 Q. And, again, let me start that  4 question over.  5 A. Yeah, because --  6 Q. My question --  7 A. -- what they specifically said was  8 that "there was a high degree of uncertainty  9 surrounding many of the individual risk  10 estimates."  11 Uncertainty could relate to power.  12 It could relate to the width of the confidence  13 intervals. It could, but it doesn't -- it doesn't  14 suggest there's systematic error in -- in the  15 studies.  16 Q. My question -- and sorry if it was  17 confusing -- is not specific as to the Taher  18 study.  19 My question is that: If there are  20 is a consistent systematic error across a group of  21 case-control and cohort studies that you're  22 combining in a meta-analysis --  23 A. I see.  24 Q. -- that combining them in a</p>	<p style="text-align: right;">Page 405</p> <p>1 they -- they have been -- they have been merged  2 together in a way that would allow you to assess a  3 test of trend with increasing exposure with  4 increasing risk of the disease.  5 So I'm not sure what they're talking  6 about in terms of a test of trend in the context  7 of that statement.  8 Q. Please turn over to page 98, the  9 Section 4.4 "Applying GRADE framework." Tell me  10 when you are there.  11 A. "Applying GRADE framework." Yes.  12 Uh-huh.  13 Q. The authors state here that they  14 apply "the GRADE framework to assess the quality  15 of the evidence derived from the studies included  16 in this review," correct?  17 A. Yes, that's what they state.  18 Q. They go on to say that:  19 "Using GRADEpro for the assessment,  20 the certainty of the evidence was classified as  21 very low."  22 Correct?  23 MR. TISI: Objection.  24 THE WITNESS: (Reviews</p>

<p style="text-align: right;">Page 406</p> <p>1 document.)</p> <p>2 Can you reread that sentence</p> <p>3 where it is? I'm not seeing it.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Sure.</p> <p>6 It's just after the sentence I</p> <p>7 read --</p> <p>8 MR. TISI: Right there.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. -- under the section "Applying GRADE</p> <p>11 framework." The first sentence. The second</p> <p>12 sentence reads --</p> <p>13 A. Oh. Yes.</p> <p>14 Q. -- "Using GRADEpro for the</p> <p>15 assessment, the certainty of the evidence was</p> <p>16 classified as very low."</p> <p>17 A. Yes, they say that.</p> <p>18 Q. Are you familiar with the GRADE</p> <p>19 framework outside of this study?</p> <p>20 A. I am not.</p> <p>21 Q. The authors a couple sentences or at</p> <p>22 least one sentence later says:</p> <p>23 "However, we deemed the findings to</p> <p>24 be subject to an appreciable risk of bias, mainly</p>	<p style="text-align: right;">Page 408</p> <p>1 a daily basis.</p> <p>2 Q. Please turn over to the next page,</p> <p>3 page 99.</p> <p>4 A. Yes.</p> <p>5 Q. The paragraph at the top begins:</p> <p>6 "Study design is a critical</p> <p>7 component in the GRADE assessment, where</p> <p>8 randomized controlled trials (RCTs) are viewed as</p> <p>9 providing considerably stronger evidence than</p> <p>10 observational studies."</p> <p>11 Do you agree with that statement?</p> <p>12 A. I do.</p> <p>13 Q. They go on to say:</p> <p>14 "As such, the evidence derived from</p> <p>15 the observational studies in this review was</p> <p>16 initially classified as being of low certainty</p> <p>17 within the GRADE framework; this was further</p> <p>18 downgraded to very low certainty in light of the</p> <p>19 risk of bias noted above."</p> <p>20 Do you see where the authors</p> <p>21 downgraded their evidence to very low certainty?</p> <p>22 A. Yeah, but again --</p> <p>23 MR. TISI: Objection.</p> <p>24 THE WITNESS: -- the next</p>
<p style="text-align: right;">Page 407</p> <p>1 due to the potential for recall bias in the</p> <p>2 included case control studies and the relatively</p> <p>3 short follow-up periods between exposure and</p> <p>4 outcome assessment in the included cohort</p> <p>5 studies."</p> <p>6 First of all, did I read that</p> <p>7 correctly?</p> <p>8 A. You did, but you failed to read the</p> <p>9 sentence before where they say:</p> <p>10 "First, we considered our findings</p> <p>11 from the meta-analysis to lack any serious issues</p> <p>12 with respect to inconsistency, indirectness, and</p> <p>13 imprecision."</p> <p>14 Q. Going to my question, though, did I</p> <p>15 read that statement correctly?</p> <p>16 A. Yes, you did.</p> <p>17 Q. Do you disagree with that statement?</p> <p>18 A. I disagree with the issue of recall</p> <p>19 bias. Although, again, when you're only looking</p> <p>20 at ever never with respect to talc exposure, there</p> <p>21 will possibly be some recall bias.</p> <p>22 But, again, as I've stated many</p> <p>23 times, I believe the risk of talc exposure is</p> <p>24 substantially due to long-term use for decades on</p>	<p style="text-align: right;">Page 409</p> <p>1 sentence says:</p> <p>2 "Despite the very low</p> <p>3 certainty assigned by the GRADE</p> <p>4 evaluation, which heavily factors</p> <p>5 evidence from RCTs."</p> <p>6 You can't do an RCT and assign</p> <p>7 women to receive or not receive talc</p> <p>8 exposure. So the grade evaluation if it</p> <p>9 relies heavily on -- on results from</p> <p>10 randomized clinical trials is going to</p> <p>11 grade, apparently from this statement,</p> <p>12 everything low that's not an RCT.</p> <p>13 BY MR. HEGARTY:</p> <p>14 Q. Please look over at or back at page</p> <p>15 98.</p> <p>16 In Footnote A at the bottom, they</p> <p>17 describe the "GRADE Working Group grades"?</p> <p>18 A. Uh-huh.</p> <p>19 Q. Correct?</p> <p>20 A. Uh-huh.</p> <p>21 Q. Yes?</p> <p>22 A. Yes, I see it. Sorry.</p> <p>23 Q. In that footnote, they describe the</p> <p>24 grade very low certainty as:</p>

<p style="text-align: right;">Page 410</p> <p>1 "We have little confidence in the  2 effect estimate: the true effect is likely to be  3 substantially different from the estimate of  4 effect."  5 Did I read that correctly?  6 A. You did.  7 Q. So the authors in this study  8 concluded that their evidence with regard to  9 talcum powder use and ovarian cancer is of very  10 low certainty, correct?  11 MR. TISI: Objection.  12 THE WITNESS: That was their  13 opinion.  14 BY MR. HEGARTY:  15 Q. Did you read when you -- sorry.  16 Strike that.  17 Did you see when you read the Health  18 Canada screening assessment that they rely or that  19 they reference this Taher study?  20 A. I believe they reference a lot of  21 studies. I don't know. I mean, I have the Health  22 Canada report and I -- I don't dispute that they  23 -- that they reference this study.  24 Q. Do you see where it says under the</p>	<p style="text-align: right;">Page 412</p> <p>1 A. Yes.  2 Q. Assume for purpose of my question  3 that the average age of women starting talcum  4 powder use on a regular basis is age 20, and the  5 average age of a tubal ligation and/or a  6 hysterectomy is in the 40s.  7 Is that 20 years of use  8 insufficient, in your view, to increase those  9 women's risk of ovarian cancer?  10 A. Not necessarily. 20 years of use  11 every day in a patent genital tract until that  12 time is a substantial amount of exposure, in my  13 view.  14 Q. In my hypothetical, if that is the  15 nature of use in the studies that we looked at  16 that have looked at patent and unpatent tubes, how  17 is then an emphasis on the finding -- findings of  18 unpatent tubes a noteworthy finding?  19 MR. TISI: Objection.  20 BY MR. HEGARTY:  21 Q. If you can understand my question?  22 MR. TISI: Misstates his  23 testimony.  24 Go ahead.</p>
<p style="text-align: right;">Page 411</p> <p>1 "Sources of funding" part of this paper that:  2 "This work was supported by Health  3 Canada as part of their Chemicals Management Plan  4 via contract number" and they list the contract  5 number?  6 A. Yes.  7 Q. "To Risk Scientists International  8 (RSI), Ottawa Canada -- Ontario, Canada"?  9 A. Yes, I see that.  10 Q. Does that indicate to you that  11 Health Canada provided funding to do this study?  12 A. Yes, they -- they did.  13 I don't believe that -- I believe  14 Health Canada is a governmental agency. Okay.  15 It's not a private foundation. It's a  16 governmental agency. Just like we are funded here  17 in the United States by the National Institutes of  18 Health for a lot of research that we do.  19 Q. We've been talking today about the  20 studies reporting on relative risk or odds ratios  21 between women with patent and women with unpatent  22 tubes, correct?  23 A. (Nods head).  24 Q. Correct?</p>	<p style="text-align: right;">Page 413</p> <p>1 THE WITNESS: Why don't you  2 repeat that question, please.  3 BY MR. HEGARTY:  4 Q. Sure.  5 If my hypothetical is accurate and  6 the women studied in those studies that have  7 looked at patent and unpatent tubes had 20 years  8 of talc exposure prior to having tubal ligation or  9 hysterectomy, how is it noteworthy to compare  10 those women to women with patent tubes?  11 MR. TISI: Objection.  12 BY MR. HEGARTY:  13 Q. If you can understand -- do you  14 understand my question?  15 A. Yeah. I think you're -- you're  16 assuming that the studies looked only at women who  17 were exposed during times when they had patent  18 tubes, and then looking at women who are only  19 exposed during times when their genital tract was  20 closed.  21 Is that what you're saying?  22 Q. Well, I'm not sure that's what I'm  23 saying, but my point -- the question I'm asking  24 you is: To the extent those -- there's</p>

<p style="text-align: right;">Page 414</p> <p>1 differences between the group who used talc for 20 2 years prior to having tubal ligation or 3 hysterectomy and those that had patent tubes, what 4 do you explain the differences to be? 5 A. Well, I believe others have 6 explained the possibility that if they're using it 7 and they do not have patent tubes, it does not 8 preclude them from exposure, particularly from 9 inhalation. 10 Q. Is it your opinion that inhalation 11 of talcum powder use can cause ovarian cancer? 12 A. There's some evidence that it was -- 13 that it's a possibility. I believe it was -- was 14 it Schildkraut's article that discussed that? 15 One of the articles did discuss that 16 as a possibility, and I didn't do an extensive 17 search on -- on inhalation of talc and its impact 18 specifically on ovarian cancer. 19 Q. Do you have an opinion one way or 20 another as to whether inhalation of talc can cause 21 ovarian cancer? 22 A. I don't have an opinion at this 23 point, but you've tweaked my interest. 24 Q. You had -- you don't make any</p>	<p style="text-align: right;">Page 416</p> <p>1 A. Well, because most of the studies 2 that have looked at this have shown that it is not 3 as strong a risk factor as that among women who 4 apply it daily on a regular basis. 5 Q. You said you reported on that data 6 in at least one of your prior studies, correct? 7 A. We have, yes. 8 Q. Is that appropriate data to look at 9 when evaluating whether there's a risk of ovarian 10 cancer with talcum powder use? 11 A. I believe so. 12 Q. We talked a moment -- talked earlier 13 in the day about whether it is necessary for talc 14 to reach the ovary for purposes of your biologic 15 plausibility assessment, and you also referenced 16 that talc can get to the fallopian tubes. 17 Do you recall that discussion? 18 A. Yes. 19 Q. Is it necessary for purposes of your 20 biologic plausibility opinion that talc at least 21 reached the fallopian tube? 22 A. I think it would be reasonable to. 23 If there were no evidence of talc reaching the 24 fallopian tubes, I would -- I would reassess that,</p>
<p style="text-align: right;">Page 415</p> <p>1 reference in your report to studies that have 2 looked at talc-dusted diaphragms or talc-dusted 3 condoms in ovarian cancer risk, correct? 4 A. In my -- in my previous research, I 5 definitely discuss that. In the report, we -- we 6 focus on -- on direct perineal application. 7 Although I would not be surprised if within my 8 report on some of these particular studies we 9 talked about the issue of exposure on diaphragms 10 or condoms. 11 But I believe in most of the 12 research that I've looked at, the risk is lower in 13 those women. Probably because of the infrequent 14 nature of the exposure. 15 Q. My question is not what the risk is 16 that's or has been reported in the study. 17 My question is: Did you do an 18 analysis in your report in this case of the 19 studies that looked at the risk of ovarian cancer 20 from women using talc-dusted diaphragms or 21 talc-dusted condoms? 22 A. I did not specifically put a section 23 in my report about that particular risk. 24 Q. Why did you not do that?</p>	<p style="text-align: right;">Page 417</p> <p>1 but the fact is there is. 2 MR. TISI: May I ask how much 3 time we have? 4 MR. HEGARTY: Let's go off the 5 record. 6 (Recess: 6:01 p.m. - 7 6:02 p.m.) 8 MR. HEGARTY: We're back on 9 the record. 10 I have some amount of time 11 left, 16 minutes, I believe, that we 12 talked about. I'm going to reserve that 13 time for any further questioning once 14 plaintiffs' counsel is finished asking or 15 doing his direct examination of 16 Dr. Harlow. 17 MR. TISI: And we will, you 18 know, I will be flexible with you as long 19 as it's not unreasonable. 20 MR. HEGARTY: Thank you. 21 (Recess: 6:03 p.m. - 22 6:04 p.m.) 23 // 24 //</p>



<p style="text-align: right;">Page 418</p> <p>1 EXAMINATION</p> <p>2 BY MR. TISI:</p> <p>3 Q. Doctor, I'm Chris Tisi. I am the</p> <p>4 attorney who is the -- who has retained you to</p> <p>5 give your expert opinion in this case.</p> <p>6 So let me just start with the big</p> <p>7 picture and perhaps maybe we can maneuver to some</p> <p>8 specific areas.</p> <p>9 You were asked a lot of questions</p> <p>10 about -- I think you talked about Weiss's study</p> <p>11 and different studies over the course of the past</p> <p>12 40, 50 years. I'm going to bring you to today and</p> <p>13 just ask you a big picture question.</p> <p>14 Based upon what's known today and</p> <p>15 having considered all the things you considered</p> <p>16 over the past 50 years of research, do you</p> <p>17 continue to believe to a reasonable degree of</p> <p>18 scientific certainty that talc is a cause of</p> <p>19 epithelial ovarian cancer?</p> <p>20 MR. HEGARTY: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: I do.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Okay. Did anything that counsel</p>	<p style="text-align: right;">Page 420</p> <p>1 A. I've looked at --</p> <p>2 MR. HEGARTY: Do you have</p> <p>3 copies of any studies you're going to</p> <p>4 use?</p> <p>5 MR. TISI: Yeah.</p> <p>6 MR. HEGARTY: Do you have</p> <p>7 copies for me?</p> <p>8 MR. TISI: I do.</p> <p>9 MR. HEGARTY: I was going to</p> <p>10 say I can find copies if I need to, but I</p> <p>11 will wait.</p> <p>12 BY MR. TISI:</p> <p>13 Q. I'm going to use by way of</p> <p>14 example -- I'm going to show you a study or -- I'm</p> <p>15 sorry. Maybe this is one in which I don't.</p> <p>16 MR. HEGARTY: Which one is it?</p> <p>17 MR. TISI: This is the 2021.</p> <p>18 This one.</p> <p>19 MS. PARFITT: Which one?</p> <p>20 O'Brien?</p> <p>21 MR. TISI: 2021.</p> <p>22 MR. HEGARTY: Who are the</p> <p>23 authors?</p> <p>24 MR. TISI: It's O'Brien</p>
<p style="text-align: right;">Page 419</p> <p>1 told -- asked you about today change that opinion</p> <p>2 at all?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay. Do you believe it's</p> <p>8 biologically plausible that talc can reach the</p> <p>9 ovaries, can cause inflammation resulting in</p> <p>10 cellular changes, enter the ovary, and -- and it's</p> <p>11 biologically plausible that that is in the chain</p> <p>12 of events leading to ovarian cancer?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form of the question.</p> <p>15 THE WITNESS: It's</p> <p>16 biologically plausible.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay. And so you were asked a lot</p> <p>19 of questions today about Dr. O'Brien.</p> <p>20 Did you look at Dr. O'Brien's</p> <p>21 research? Did you look at Dr. O'Brien's research</p> <p>22 over -- over time?</p> <p>23 A. Yes.</p> <p>24 Q. Okay.</p>	<p style="text-align: right;">Page 421</p> <p>1 Weinberg, D'Aloisio Moore, and Sandler.</p> <p>2 MR. HEGARTY: I think I have a</p> <p>3 copy. If you don't have a copy, I think</p> <p>4 I have one. I can find it.</p> <p>5 MR. TISI: Okay. I'm going to</p> <p>6 have this marked as Plaintiff's Exhibit</p> <p>7 Number 1.</p> <p>8 Do you have a copy of that?</p> <p>9 THE WITNESS: Yes, I do.</p> <p>10 MR. TISI: Can I mark yours as</p> <p>11 Exhibit Number 1, please?</p> <p>12 (Document marked for</p> <p>13 identification as Exhibit P1.)</p> <p>14 MR. HEGARTY: Do you have a</p> <p>15 copy?</p> <p>16 MR. TISI: You can read over</p> <p>17 his shoulder if you don't mind.</p> <p>18 MR. HEGARTY: Yeah, I do want</p> <p>19 to when you're done. Is your copy marked</p> <p>20 on?</p> <p>21 MR. TISI: I would give you my</p> <p>22 copy.</p> <p>23 MR. HEGARTY: I just want to</p> <p>24 look at back over it.</p>

<p style="text-align: right;">Page 422</p> <p>1 MR. TISI: Sure.</p> <p>2 MR. HEGARTY: Beyond what</p> <p>3 you're asking him about.</p> <p>4 MR. TISI: No problem.</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm going to -- this is an article</p> <p>7 that Dr. O'Brien and colleagues wrote on "The</p> <p>8 association between douching, general talc use,</p> <p>9 and the risk of prevalent and incident cervical</p> <p>10 cancer."</p> <p>11 Have you seen this article before?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. I'm going to refer you to the</p> <p>14 second page. She says -- she describes -- she</p> <p>15 describes her own research as well as biologic</p> <p>16 plausibility, and I'm going to read it to you and</p> <p>17 ask whether you agree with it. Okay?</p> <p>18 A. Yes.</p> <p>19 Q. It says:</p> <p>20 "Genital talc use could also</p> <p>21 plausibly contribute to cervical cancer risk."</p> <p>22 She's talking about cervical cancer</p> <p>23 there, right?</p> <p>24 A. Uh-huh.</p>	<p style="text-align: right;">Page 424</p> <p>1 1994.</p> <p>2 BY MR. TISI:</p> <p>3 Q. It says:</p> <p>4 "Additional or more severe adverse</p> <p>5 effects could occur if the talc contains asbestos,</p> <p>6 a known carcinogen sometimes mined in the same</p> <p>7 location as talc."</p> <p>8 Do you see that?</p> <p>9 A. Yes, I do.</p> <p>10 MR. HEGARTY: Objection to the</p> <p>11 form.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. Does that add to the biologic</p> <p>14 plausibility that talc is a cause of ovarian</p> <p>15 cancer and is that something that you wrote about</p> <p>16 in your article in 1989?</p> <p>17 A. Yes.</p> <p>18 MR. HEGARTY: Objection to the</p> <p>19 form.</p> <p>20 THE WITNESS: It is something</p> <p>21 that I mentioned in 1989 in my article.</p> <p>22 BY MR. TISI:</p> <p>23 Q. And then she goes on to say:</p> <p>24 "The epidemiologic literature</p>
<p style="text-align: right;">Page 423</p> <p>1 Q. Okay. But then she goes on to say:</p> <p>2 "Talc applied to underwear, sanitary</p> <p>3 napkins, diaphragms, or directly to the perineal</p> <p>4 region can enter the vagina and travel up the</p> <p>5 reproductive tract."</p> <p>6 Is that consistent with what you</p> <p>7 described in your literature 20, 30 years ago?</p> <p>8 MR. HEGARTY: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. Secondly says:</p> <p>13 "Talc particles may act as</p> <p>14 irritants, inciting an inflammatory response and</p> <p>15 potentially affecting individuals'</p> <p>16 susceptibility."</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. Okay. Is that something you wrote</p> <p>20 about 20, 30, or 40 years ago?</p> <p>21 MR. HEGARTY: Objection to the</p> <p>22 form.</p> <p>23 THE WITNESS: I for sure</p> <p>24 mentioned it in my review article in</p>	<p style="text-align: right;">Page 425</p> <p>1 supports a possible positive association between</p> <p>2 general talc use and ovarian cancer."</p> <p>3 Do you see that?</p> <p>4 A. Yes, Do I.</p> <p>5 Q. And if you look at the citation, she</p> <p>6 cites her own pooled analysis that counsel was</p> <p>7 asking you about before, correct?</p> <p>8 A. That's correct, and the Terry study.</p> <p>9 Q. Okay. Now, you --</p> <p>10 A. Are we done with this?</p> <p>11 Q. Yes, we are.</p> <p>12 A. Okay.</p> <p>13 Q. In fact, she's made that -- that</p> <p>14 comment on more than one occasion since publishing</p> <p>15 her article, correct?</p> <p>16 MR. HEGARTY: Objection to the</p> <p>17 form.</p> <p>18 THE WITNESS: I would need to</p> <p>19 see it.</p> <p>20 MR. TISI: Okay. Okay. I</p> <p>21 have another. I have another copy of it.</p> <p>22 Here you go.</p> <p>23 MR. HEGARTY: Okay. I'll give</p> <p>24 you your copy back. Is that Exhibit</p>

<p style="text-align: right;">Page 426</p> <p>1 Number 1?</p> <p>2 THE WITNESS: Oh, I've got</p> <p>3 the one that says exhibit on it. Here</p> <p>4 you go. Oh, it's Exhibit 1. Do I give</p> <p>5 you this back?</p> <p>6 BY MR. TISI:</p> <p>7 Q. No, just leave it.</p> <p>8 All right. So --</p> <p>9 MR. HEGARTY: Are you using</p> <p>10 that as P1 or 1?</p> <p>11 MR. TISI: P1. Plaintiff's 1.</p> <p>12 MR. HEGARTY: I just want to</p> <p>13 make sure that when we read the record we</p> <p>14 don't --</p> <p>15 MR. TISI: Yeah, if I have to</p> <p>16 go back and follow your system, I won't</p> <p>17 be able to.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. So let me go back and ask you</p> <p>20 some things.</p> <p>21 He asked you some questions about</p> <p>22 whether you were a toxicologist, whether you were</p> <p>23 a cellular biologist, whether you're a medical</p> <p>24 doctor.</p>	<p style="text-align: right;">Page 428</p> <p>1 questions by counsel about whether you had ever</p> <p>2 made any effort to educate your colleagues with</p> <p>3 the medical and scientific community about the</p> <p>4 potential problems of talc and ovarian cancer.</p> <p>5 Do you remember those questions?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: Yes, I remember</p> <p>9 those questions.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. Now, taking those two things,</p> <p>12 together talking about the biologic plausibility</p> <p>13 of talc and ovarian cancer and the question of</p> <p>14 letting people know about your views, is that</p> <p>15 something you did in the published medical</p> <p>16 literature before you were ever contacted by me,</p> <p>17 Ms. Parfitt, or anybody else?</p> <p>18 MR. HEGARTY: Objection to the</p> <p>19 form.</p> <p>20 THE WITNESS: Well, in my</p> <p>21 published article, my 1989 article, my</p> <p>22 1992 article, my 1994 article and the</p> <p>23 article I did with Dr. Cramer in 1999, we</p> <p>24 always ended with our belief that this</p>
<p style="text-align: right;">Page 427</p> <p>1 Remember all those questions?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Doctor, in the course of</p> <p>4 being an epidemiologist for your entire career, do</p> <p>5 you have opportunity to synthesize the biologic</p> <p>6 evidence to evaluate in connection with the</p> <p>7 statistical evidence that you gather as an</p> <p>8 epidemiologist?</p> <p>9 MR. HEGARTY: Objection to the</p> <p>10 form.</p> <p>11 THE WITNESS: It's the</p> <p>12 standard of practice.</p> <p>13 Anytime I do an analysis and</p> <p>14 come forward with the research findings,</p> <p>15 a section of the discussion needs to be</p> <p>16 related to the biological rationale for</p> <p>17 why a particular association would exist,</p> <p>18 and to do that, one needs to review the</p> <p>19 literature on whether it be animal</p> <p>20 studies or cell-based studies, or other</p> <p>21 studies that would provide evidence that</p> <p>22 the association makes biological sense.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Okay. And you were also asked some</p>	<p style="text-align: right;">Page 429</p> <p>1 was an exposure that women should avoid.</p> <p>2 BY MR. TISI:</p> <p>3 Q. And you talked about asbestos</p> <p>4 contamination in those articles, correct?</p> <p>5 A. Yes.</p> <p>6 Q. You talked about biologic</p> <p>7 plausibility including the migration, correct?</p> <p>8 MR. HEGARTY: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: As I do in all</p> <p>11 of my research articles.</p> <p>12 BY MR. TISI:</p> <p>13 Q. You talked about -- you talked about</p> <p>14 all the things that counsel asked you about today</p> <p>15 long before you were ever retained by us, true?</p> <p>16 MR. HEGARTY: Objection to the</p> <p>17 form.</p> <p>18 THE WITNESS: That's correct.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. For example, let me show you</p> <p>21 what I have marked as Exhibit Number P2, which is</p> <p>22 your article from 1989.</p> <p>23 (Document marked for</p> <p>24 identification as Exhibit P2.)</p>

<p style="text-align: right;">Page 430</p> <p>1 BY MR. TISI:</p> <p>2 Q. And I'm not going to go over every</p> <p>3 aspect of it, but you're familiar with this</p> <p>4 article, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And this is a study called "A</p> <p>7 Case-Control Study of Borderline Ovarian Tumors:</p> <p>8 The Influence of Perineal Exposure to Talc,"</p> <p>9 correct?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And this was 1989, correct?</p> <p>12 A. That's correct.</p> <p>13 Q. Okay. George Bush the first was</p> <p>14 president, right?</p> <p>15 A. I don't recall. (Laugh).</p> <p>16 Q. Long time ago, fair?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And you write at the end of</p> <p>19 your -- and you talk about that there was an</p> <p>20 increased incidence in borderline ovarian tumors</p> <p>21 in women who had been exposed to deodorizing</p> <p>22 powders, correct?</p> <p>23 A. It was not incidence. It was risk.</p> <p>24 Q. Risk. True?</p>	<p style="text-align: right;">Page 432</p> <p>1 Q. Okay. So one of the things you</p> <p>2 talked about in your early literature is whether</p> <p>3 or not asbestos was in these products that were</p> <p>4 used perineally, correct?</p> <p>5 MR. HEGARTY: Objection to the</p> <p>6 form.</p> <p>7 THE WITNESS: That is</p> <p>8 correct, and I believe in the body of the</p> <p>9 discussion I talk about the evidence for</p> <p>10 that.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. Let's go to the next one,</p> <p>13 1982, which I think was previously marked, but I'm</p> <p>14 going to mark it again because I don't want to dig</p> <p>15 through my stuff.</p> <p>16 A. 1992?</p> <p>17 Q. 1992. This is an article "Perineal</p> <p>18 Exposure to Talc and Ovarian Cancer Risk," Bernard</p> <p>19 Harlow, and this will be Exhibit P3.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit P3.)</p> <p>22 BY MR. TISI:</p> <p>23 Q. And what was the significance of</p> <p>24 this study, Doctor?</p>
<p style="text-align: right;">Page 431</p> <p>1 A. Yes.</p> <p>2 Q. Okay. But I want to refer you to</p> <p>3 the very end of the article and, again, you were</p> <p>4 not retained as an expert at the time, correct?</p> <p>5 A. Correct.</p> <p>6 Q. In fact, there was -- I'm going to</p> <p>7 represent to you that no case of ovarian cancer</p> <p>8 and talc wasn't ever filed until 2009.</p> <p>9 All your published literature, with</p> <p>10 the exception of the letter to the editor, was</p> <p>11 published before there was any talc litigation,</p> <p>12 correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And you write at the end, the</p> <p>15 last sentence. I'll read it into the record.</p> <p>16 "Although these data need</p> <p>17 replication, they raise the possibility that the</p> <p>18 risk of ovarian tumors in women who apply</p> <p>19 deodorizing powder to the perineum may not relate</p> <p>20 to talc per se but rather to asbestos</p> <p>21 contamination and/or a substances or substances</p> <p>22 used specifically for deodorization."</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 433</p> <p>1 A. Well, I believe this was one of the</p> <p>2 -- one of the first studies to really try to tease</p> <p>3 out the dose-response association with talc</p> <p>4 applications by looking at it excluding use after</p> <p>5 hysterectomy or tubal ligation and during</p> <p>6 non-ovulatory months where we see an important</p> <p>7 dose response.</p> <p>8 Q. And you saw anywhere between a --</p> <p>9 you saw an increased risk in dealing with women</p> <p>10 with patent intact reproductive tracts of ovarian</p> <p>11 cancer, true?</p> <p>12 MR. HEGARTY: Objection to the</p> <p>13 form.</p> <p>14 THE WITNESS: Yes, but it</p> <p>15 wasn't -- it wasn't specifically asking</p> <p>16 about that. It was actually calculating</p> <p>17 applications that were used during</p> <p>18 periods when there was a patent genital</p> <p>19 tract.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay. And that brings me to a</p> <p>22 question that counsel was asking a lot of</p> <p>23 questions about.</p> <p>24 He asked you about years of use. He</p>

<p style="text-align: right;">Page 434</p> <p>1 asked you about frequency of use.</p> <p>2 As an epidemiologist, you understand</p> <p>3 that exposure -- do you understand that exposure</p> <p>4 to a potential toxin is a -- is the important</p> <p>5 consideration with respect to dose response, true?</p> <p>6 MR. HEGARTY: Objection to the</p> <p>7 form.</p> <p>8 THE WITNESS: Yes, exposure.</p> <p>9 Not just how many years you've used it or</p> <p>10 how frequently you use it, but the</p> <p>11 combination of both that allows you to</p> <p>12 get an accurate assessment of exposure.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. And that's what you tried to</p> <p>15 do in this particular study, correct?</p> <p>16 A. Correct.</p> <p>17 Q. All right. And at the end of the</p> <p>18 study, you state -- again, this is long before</p> <p>19 litigation in 1992:</p> <p>20 "Given the poor prognosis for women</p> <p>21 for ovarian cancer, any potentially harmful</p> <p>22 exposures should be avoided, particularly those</p> <p>23 with limited benefits. For this reason, we</p> <p>24 discourage the use of talc in genital hygiene,</p>	<p style="text-align: right;">Page 436</p> <p>1 form.</p> <p>2 THE WITNESS: I did not think</p> <p>3 of it as the talc industry. I thought of</p> <p>4 it as the Food and Drug Administration</p> <p>5 and the International Society of</p> <p>6 Regulatory Toxicology &amp; Pharmacology. I</p> <p>7 did not --</p> <p>8 BY MR. TISI:</p> <p>9 Q. At the time.</p> <p>10 A. At the time, I did not think to</p> <p>11 myself, oh, this is an industry-sponsored</p> <p>12 conference.</p> <p>13 Q. Okay.</p> <p>14 A. I basically wanted -- I was pleased</p> <p>15 to be invited, was pleased to have the opportunity</p> <p>16 to convey my findings, with the hope that it would</p> <p>17 lead to potential mitigation of the exposure.</p> <p>18 Q. Okay. And so when you went into</p> <p>19 this -- when you went into this meeting, you were</p> <p>20 pretty clear that not only was there an</p> <p>21 association in people who had been exposed --</p> <p>22 women who had been exposed, but that for</p> <p>23 precautionary reasons they shouldn't be using it,</p> <p>24 true?</p>
<p style="text-align: right;">Page 435</p> <p>1 particularly as a daily habit."</p> <p>2 Correct?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And so when counsel asked</p> <p>5 you, did you ever tell the medical and scientific</p> <p>6 community about your point of view, you actually</p> <p>7 published in the peer-reviewed literature about</p> <p>8 that, correct?</p> <p>9 MR. HEGARTY: Objection to the</p> <p>10 form. Misstates my question.</p> <p>11 You can answer.</p> <p>12 THE WITNESS: You correctly</p> <p>13 summarize what I had indicated in my</p> <p>14 published work.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. So now let's talk about the</p> <p>17 Carr, the IS RTP conference.</p> <p>18 You were asked to attend that</p> <p>19 meeting, correct?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Is it your understanding that</p> <p>22 this was primarily a meeting that was convened</p> <p>23 between the talc industry and the FDA, correct?</p> <p>24 MR. HEGARTY: Objection to the</p>	<p style="text-align: right;">Page 437</p> <p>1 MR. HEGARTY: Objection to the</p> <p>2 form.</p> <p>3 THE WITNESS: I had stated</p> <p>4 that in my 1989 article. I had stated</p> <p>5 that in my 1992 article. And when I went</p> <p>6 into the conference in 1994, my views had</p> <p>7 not changed.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Now, in the article itself -- and do</p> <p>10 you have a copy of the article in front of you?</p> <p>11 A. The summation of it by Carr or</p> <p>12 the -- my -- my article? My review?</p> <p>13 MR. TISI: I'm going to mark</p> <p>14 it as Exhibit Number 4.</p> <p>15 (Document marked for</p> <p>16 identification as Exhibit P4.)</p> <p>17 MR. HEGARTY: Is that P4?</p> <p>18 MR. TISI: P4.</p> <p>19 MR. HEGARTY: So we don't have</p> <p>20 two 4s.</p> <p>21 THE WITNESS: So that's the --</p> <p>22 MR. TISI: P4. I think it's</p> <p>23 your Number 8.</p> <p>24 THE WITNESS: Right.</p>



<p style="text-align: right;">Page 438</p> <p>1 MR. HEGARTY: I trust you.</p> <p>2 THE WITNESS: Yes, that's</p> <p>3 this. Yes, that's the summary. The</p> <p>4 summary by Rapporteur Jelleff Carr.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Now, in here it says -- on page 215</p> <p>7 on the left-hand side, it says:</p> <p>8 "Dr. Hartge (National Cancer</p> <p>9 Institute) and Dr. Harlow (Harvard University)</p> <p>10 presented a review of epidemiologic studies --</p> <p>11 including their own original studies -- pertaining</p> <p>12 to perineal talc exposure and ovarian cancer</p> <p>13 risk."</p> <p>14 A. Can you show me where that is,</p> <p>15 please?</p> <p>16 Q. On the left-hand side.</p> <p>17 A. Yeah.</p> <p>18 Q. The last full paragraph on page 215.</p> <p>19 A. Oh, 215. I'm sorry.</p> <p>20 Okay. Dr. Hartge and Dr. Harlow. I</p> <p>21 got the paragraph. Go ahead.</p> <p>22 Q. Did this article at all explain what</p> <p>23 your presentation was so that people subsequent to</p> <p>24 this hearing could hear about your presentation</p>	<p style="text-align: right;">Page 440</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. Did you ultimately write a</p> <p>5 full review of what it was that you -- that you</p> <p>6 presented at the meeting in 2014?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. In fact, just to be -- just</p> <p>9 to be clear, the only reference in this article</p> <p>10 was -- was to whom?</p> <p>11 A. Dr. Rothman.</p> <p>12 Q. Okay. Somebody who counsel implied</p> <p>13 may have been statistically unsophisticated.</p> <p>14 Would you ever classify Dr. Rothman</p> <p>15 or yourself as statistically unsophisticated?</p> <p>16 MR. HEGARTY: Objection to the</p> <p>17 form.</p> <p>18 THE WITNESS: No.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Between the two of you, would</p> <p>21 you maybe have published perhaps anywhere between</p> <p>22 500 and a thousand articles in the peer-reviewed</p> <p>23 literature?</p> <p>24 MR. HEGARTY: Objection to</p>
<p style="text-align: right;">Page 439</p> <p>1 about the risks?</p> <p>2 MR. HEGARTY: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: No.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay.</p> <p>7 A. There was nothing other than</p> <p>8 indicating that we presented original research --</p> <p>9 Q. Okay.</p> <p>10 A. -- and that the studies reviewed</p> <p>11 brought to light the many interpretative</p> <p>12 difficulties of epidemiology as an observational</p> <p>13 science and are detailed in the papers by Harlow</p> <p>14 and Hartge appear in this issue of the journal.</p> <p>15 They only said -- they only put into</p> <p>16 this review that all we talked about were the</p> <p>17 concerns.</p> <p>18 Q. That doesn't --</p> <p>19 A. Whereas, we talked about the</p> <p>20 evidence in a balanced and, I believe,</p> <p>21 academically appropriate manner.</p> <p>22 Q. Did you feel that this summary was</p> <p>23 fair and balanced?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 441</p> <p>1 form.</p> <p>2 THE WITNESS: Yes.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. He's published textbooks and</p> <p>5 the textbooks that are used in medical schools</p> <p>6 throughout the country?</p> <p>7 A. And in schools of public health --</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: -- across the</p> <p>11 country.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. Now, it talks about at the</p> <p>14 end here, it says:</p> <p>15 "The possibility of an association</p> <p>16 of talc exposure and ovarian cancer is an</p> <p>17 important hypothesis of potential public health</p> <p>18 importance. However, this association remains a</p> <p>19 research hypothesis whose verification or</p> <p>20 falsification needs additional study."</p> <p>21 And it goes on to say that there is</p> <p>22 "epidemiologic study have provided weak and</p> <p>23 conflicting risk signals" for this association,</p> <p>24 "and it is unlikely that further studies" would</p>

<p style="text-align: right;">Page 442</p> <p>1 yield any additional concern.</p> <p>2 Do you see that at the very end of</p> <p>3 the paragraph?</p> <p>4 A. Yes.</p> <p>5 "For epidemiology, further</p> <p>6 refinements may be possible in the selection and</p> <p>7 characterization of control subjects and in the</p> <p>8 accounting of possible confounders and biases.</p> <p>9 However, epidemiologic studies have provided weak</p> <p>10 and conflicting risk signals for this association,</p> <p>11 and it is unlikely that further studies may prove</p> <p>12 adequate to raise concern at a level sufficient to</p> <p>13 warrant regulatory or public health measures."</p> <p>14 Q. In fact -- in fact, after this</p> <p>15 particular study, there were literally dozens of</p> <p>16 studies that were funded by -- by institutions</p> <p>17 throughout the country, including National Cancer</p> <p>18 Institute, correct?</p> <p>19 MR. HEGARTY: Objection to the</p> <p>20 form.</p> <p>21 THE WITNESS: There were.</p> <p>22 There were.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Do you think --</p>	<p style="text-align: right;">Page 444</p> <p>1 Q. And you'll see at the very first</p> <p>2 part of it, it says -- it says:</p> <p>3 "Presented, in part" --</p> <p>4 Footnote 1 says:</p> <p>5 "Presented, in part, at the</p> <p>6 International Society of Regulatory Toxicology and</p> <p>7 Pharmacology," referring to this meeting, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And it was your goal here is</p> <p>10 to -- to communicate what it was you were trying</p> <p>11 to communicate at that meeting, correct?</p> <p>12 MR. HEGARTY: Objection to the</p> <p>13 form.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. And if you look, it talks</p> <p>17 about, for example, on the right-hand side studies</p> <p>18 which showed talc particles in the ovaries going</p> <p>19 back to 1979, a study by Henderson in 1979,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. You didn't have to be -- you</p> <p>23 didn't have to be a pathologist to read that</p> <p>24 study, right?</p>
<p style="text-align: right;">Page 443</p> <p>1 A. But I'd also like to state that in</p> <p>2 this article, we actually did do an assessment of</p> <p>3 the research that had been published as of this</p> <p>4 date and all of the studies, except one, showed a</p> <p>5 positive association.</p> <p>6 Q. Okay.</p> <p>7 A. So to the extent that -- that --</p> <p>8 that further studies may prove adequate to raise</p> <p>9 concern at a level sufficient to warrant</p> <p>10 regulatory is not necessary is -- or even to</p> <p>11 suggest that we need is to suggest that no further</p> <p>12 studies are needed because the evidence is not</p> <p>13 there. When, in fact, in the article that I</p> <p>14 present -- in my presentation, I actually showed a</p> <p>15 number of studies, not just mine, that showed</p> <p>16 reasonable consistency and has been -- has been</p> <p>17 duplicated since then.</p> <p>18 Q. Let me show you Exhibit Number 5,</p> <p>19 which is your review article --</p> <p>20 A. Yeah.</p> <p>21 Q. -- that came out of this.</p> <p>22 (Document marked for</p> <p>23 identification as Exhibit P5.)</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 445</p> <p>1 MR. HEGARTY: Objection to the</p> <p>2 form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. You talked about asbestos on</p> <p>6 the next page and the fact that it could</p> <p>7 potentially migrate, correct?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. You talked about biologic</p> <p>13 plausibility of -- of asbestos causing ovarian</p> <p>14 cancer, correct?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I did.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. You talked about and you</p> <p>20 finally came out with -- and on page 256 on the</p> <p>21 left-hand side.</p> <p>22 A. Uh-huh.</p> <p>23 Q. You say:</p> <p>24 "Because the risk of any one outcome</p>

<p style="text-align: right;">Page 446</p> <p>1 is dependent upon both the frequency and length of 2 exposure." 3 You talked about why you did both of 4 those things, correct? 5 A. Yes. 6 Q. Is one of the flaws in the studies 7 that you've looked at to date that they either 8 measured length or frequency but not both 9 together? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: I believe 13 that's a limitation. 14 BY MR. TISI: 15 Q. Okay. But you tried to do that in 16 your own studies, correct? 17 A. Yes. 18 Q. And what did you find in your own 19 studies in the 1990s? 20 A. We found the dose response -- 21 Q. Okay. 22 A. -- when there was an open genital 23 tract. 24 Q. And, in fact, you put that in your</p>	<p style="text-align: right;">Page 448</p> <p>1 time was whether or not they adjusted for these 2 confounders, true? 3 A. Yes. 4 Q. In fact, you didn't have to be -- do 5 a complete comprehensive review of all the medical 6 literature of douching to know that you had to 7 adjust for douching, correct? 8 MR. HEGARTY: Objection to the 9 form. 10 THE WITNESS: To know that I 11 need to determine whether adjusting for 12 douching would impact my estimates. 13 BY MR. TISI: 14 Q. Okay. You talk about in this 15 article in 1995 the recollection of talc 16 exposures. 17 Do you see that? 18 A. Where are we talking about now? 19 Q. On page 257. 20 A. Oh, 257. Where are we? Where are 21 we now? 22 Q. On page 257. 23 A. Yes. 24 Q. The bottom to the next page,</p>
<p style="text-align: right;">Page 447</p> <p>1 article here. It says: 2 "There was a sizable increase in 3 risk in women with more than 10,000 applications 4 of talc which persisted after multivariate 5 adjustment for parity, education, marital status, 6 douching, weight, and use of sanitary napkins." 7 Do you see that? 8 A. Yes, I do. 9 Q. Now, counsel asked you whether or 10 not you looked at the literature relating to 11 things like douching, weight, and the risks of 12 ovarian cancer, true? 13 MR. HEGARTY: Objection to the 14 form. 15 THE WITNESS: In -- in 16 preparation of the report that I did? 17 BY MR. TISI: 18 Q. Right. 19 A. No, I didn't do that for preparation 20 of the report. I obviously did that in deciding 21 what potential covariates we should adjust for in 22 our analyses in this, in the 1992 paper. 23 Q. In fact, one of the things you 24 looked at when you looked at these studies over</p>	<p style="text-align: right;">Page 449</p> <p>1 correct? 2 A. Where it starts "Thus the basic 3 design"? 4 Q. On the very bottom. I'm sorry. It 5 says "Recollection of Talc Exposure." 6 On the bottom right-hand side. 7 A. Oh, I'm sorry. Got it. 8 Q. On page 257 going on to the next 9 page. 10 A. Yes. Yes, yes, yes. I'm there. 11 I'm there. Yes. 12 Q. Now, you offer the opinion that 13 today that misclassification because of recall 14 bias differentially in the case-control studies 15 might be a problem if it was not a routine or 16 habit of a woman, but if something is routine, it 17 would be not as much of a problem, correct? 18 A. Yes. 19 MR. HEGARTY: Objection to the 20 form. 21 BY MR. TISI: 22 Q. Is that something you wrote right 23 here at the bottom of page 250 -- excuse me -- 258 24 on the left-hand side when you say:</p>

<p style="text-align: right;">Page 450</p> <p>1 "Differential misclassification and 2 random error are most likely to occur if the 3 question is too long or too vague and if the 4 behavior itself is intermittent and trivial." 5 A. Correct. 6 Q. Okay. Do you see that? 7 A. Yes. 8 Q. Okay. And you also noted on the top 9 part that the risk -- 10 A. Where are you referring to now? 11 Q. In the chart, Table 3. 12 A. Oh, Table 3, yes. 13 Q. That people with prior to tubal 14 ligation, hysterectomy, and during ovulatory 15 periods only, the risk for greater than 10,000 16 applications was 2.8. 17 Do you see that? 18 A. Yes. 19 Q. Okay. Now, at the summary of your 20 article, you indicated what you thought was the 21 range of relative risks based upon the literature 22 existed at that time, correct? 23 A. Yes. 24 MR. HEGARTY: Objection to the</p>	<p style="text-align: right;">Page 452</p> <p>1 the meeting. 2 Q. So the point is here do you feel 3 that the -- if anybody were to -- first of all, 4 Dr. Carr was not an employee of the FDA, the 5 person who took these minutes, correct? 6 MR. HEGARTY: Objection to the 7 form. 8 THE WITNESS: I have no idea 9 who Dr. -- I don't even know if it's 10 Dr. Carr. I don't know who that person 11 was. 12 BY MR. TISI: 13 Q. Was there anything in the 14 presentations that were made that changed your 15 view that women ought to be -- that risks -- that 16 the risks ought to be mitigated based upon at 17 least what's available 30, 40 years ago -- 18 MR. HEGARTY: Objection. 19 BY MR. TISI: 20 Q. -- after going to this meeting at 21 the FDA? 22 MR. HEGARTY: Objection to the 23 form. 24 THE WITNESS: Can you repeat</p>
<p style="text-align: right;">Page 451</p> <p>1 form. 2 BY MR. TISI: 3 Q. You mentioned several times today 4 that you thought that risk was between 1.0, 1.8, 5 correct? 6 A. Yes. 7 MR. HEGARTY: Objection to the 8 form. 9 BY MR. TISI: 10 Q. You wrote that back in 1995, 11 correct, in this article? 12 MR. HEGARTY: Objection to the 13 form. 14 THE WITNESS: And I believe I 15 presented it at the -- at the conference 16 as well. 17 BY MR. TISI: 18 Q. That wasn't in the summary of the -- 19 of the conference, was it? 20 A. No, but it was in the minutes of 21 the -- the -- what do they call it? Minutes of 22 the meeting. 23 Q. Right. 24 A. Or the transcript. Transcript of</p>	<p style="text-align: right;">Page 453</p> <p>1 the question? I'm sorry. 2 BY MR. TISI: 3 Q. Yeah. 4 Is there anything that you heard at 5 that meeting that changed your view expressed in 6 your 1992 letter -- 7 A. Article. 8 Q. -- article that women should not use 9 talcum powder products because of the risk of 10 cancer? 11 A. There was nothing -- 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: -- that changed 15 my view that women should curtail, if not 16 completely abstain from, perineal 17 application of talcum powder. 18 BY MR. TISI: 19 Q. In fact, you reiterated that in your 20 1999 article, correct? 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: Yes, we do. 24 MR. TISI: I'm going to show</p>

<p style="text-align: right;">Page 454</p> <p>1 you that article, Exhibit Number 5.  2 MR. HEGARTY: I have Exhibit  3 Number 6, P6.  4 MR. TISI: Oh. Exhibit  5 Number 6. I'm sorry.  6 MR. HEGARTY: I have the last  7 article you designated as P5.  8 (Document marked for  9 identification as Exhibit P6.)  10 BY MR. TISI:  11 Q. Okay. This is P6. It's entitled  12 "Genital Talc Exposure and Risk of Ovarian  13 Cancer." This is the 1990 article by Dr. Cramer.  14 Do you see that?  15 A. Yes.  16 Q. Now, you were asked several  17 questions about whether Dr. Cramer was an expert  18 for plaintiffs.  19 You know that, right?  20 A. Yes.  21 Q. Again, I'm going to represent to you  22 that the first case for ovarian cancer had not  23 even been filed until at least 10, 15 years after  24 this article was published.</p>	<p style="text-align: right;">Page 456</p> <p>1 A. It means that "Excludes applications  2 following hysterectomy or tubal ligation and  3 applications during pregnancy and periods of oral  4 contraceptive use."  5 Q. Okay. Why did you do that?  6 A. Because women would not necessarily  7 be ovulating and the idea the potential  8 possibilities that with the talc migrating during  9 ovulatory times, the talc particulates have the  10 opportunity to embed into the inclusion cysts  11 after ovulation.  12 Q. Okay. And so this was a recognition  13 that there was -- was this a recognition that  14 there was a biologically plausible mechanism that  15 talc applied perineally could -- could travel up  16 the -- up the genital tract, reach the ovaries,  17 and you wanted to test that hypothesis in this  18 study, correct?  19 MR. HEGARTY: Objection to the  20 form.  21 THE WITNESS: Yes.  22 BY MR. TISI:  23 Q. Okay. And when you looked at  24 applications with less than 3,000 applications,</p>
<p style="text-align: right;">Page 455</p> <p>1 Do you have any reason to believe  2 that Dr. Cramer was an expert or consultant in  3 talc litigation at the time you wrote this  4 article?  5 MR. HEGARTY: Objection to the  6 form.  7 THE WITNESS: No.  8 BY MR. TISI:  9 Q. Okay. Now, in this article, you  10 concluded that there was, in fact, a dose response  11 when considering all application for women  12 particularly with patent tubes, correct?  13 MR. HEGARTY: Objection to the  14 form.  15 THE WITNESS: That is  16 correct.  17 BY MR. TISI:  18 Q. Would you go to page -- Table III,  19 please?  20 A. Uh-huh.  21 Q. It says when you censured patients.  22 At the very bottom it says "Application censured."  23 Could you tell what that means?  24 Could you tell us what that means?</p>	<p style="text-align: right;">Page 457</p> <p>1 what did you see?  2 A. We saw the highest adjusted odds  3 ratio being in those that had greater than 10,000  4 applications when limiting this exposure  5 assessment.  6 Q. Okay. Did you see a dose response  7 when you compared 3,000, 3,000 to 10,000, and  8 greater than 10,000?  9 A. The risks --  10 MR. HEGARTY: Objection to the  11 form.  12 THE WITNESS: The risks went  13 from 1.54 to 1.72 to 1.8.  14 BY MR. TISI:  15 Q. Were they all statistically  16 significant?  17 A. The confidence intervals did not --  18 included 1.  19 Q. Okay.  20 A. Not -- yes, included 1 in all of  21 them.  22 Q. Now, counsel was asking questions  23 about your methodology.  24 You remember that? Your causal</p>



<p style="text-align: right;">Page 458</p> <p>1 methodology?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Here in your article, you</p> <p>4 describe the causal methodology that you, in fact,</p> <p>5 used in this case, correct?</p> <p>6 MR. HEGARTY: Objection to the</p> <p>7 form.</p> <p>8 THE WITNESS: In this 1999</p> <p>9 paper, I followed the approach that I've</p> <p>10 used for all of the research in trying to</p> <p>11 interpret the findings in the context of</p> <p>12 potential biases.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Let's look at page 353 of your</p> <p>15 article, please, under the "Discussion" section.</p> <p>16 A. Uh-huh.</p> <p>17 Q. It says:</p> <p>18 "In our discussion, we will examine</p> <p>19 whether this association satisfies traditional</p> <p>20 criteria for a causal association including</p> <p>21 consistency and strength of the association,</p> <p>22 potential biases, dose response and biologic</p> <p>23 credibility."</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 460</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 BY MR. TISI:</p> <p>4 Q. That's what you explained in your --</p> <p>5 in your expert report?</p> <p>6 A. In the methodology section of that</p> <p>7 report, yes.</p> <p>8 Q. And it's what was published in the</p> <p>9 peer-reviewed -- peer-reviewed literature; is that</p> <p>10 correct?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: Published in</p> <p>14 this paper in 1999.</p> <p>15 BY MR. TISI:</p> <p>16 Q. By the way, counsel spent a lot of</p> <p>17 time asking about the National Cancer Institute</p> <p>18 and how important an agency that is.</p> <p>19 Could you tell us who funded your</p> <p>20 research in 1999?</p> <p>21 A. The National Cancer Institute.</p> <p>22 Q. Thank you very much.</p> <p>23 Oh, and by the way, at the very end</p> <p>24 of the article, they talk about you provide a</p>
<p style="text-align: right;">Page 459</p> <p>1 A. Yes, I do.</p> <p>2 Q. Are those the very same things when</p> <p>3 you published those -- those in your peer-reviewed</p> <p>4 paper that you applied when you -- you and</p> <p>5 Dr. Rothman got together and re-reviewed the</p> <p>6 evidence in 2023?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: That's correct.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. So you looked at primarily --</p> <p>12 you didn't list each and every one of the</p> <p>13 Bradford-Hill factors, right?</p> <p>14 You talked about primarily strength,</p> <p>15 consistency, biologic plausibility, and dose</p> <p>16 response and whether or not there was evidence of</p> <p>17 a bias, correct?</p> <p>18 A. That's correct.</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 BY MR. TISI:</p> <p>22 Q. That would otherwise explain the</p> <p>23 association?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 461</p> <p>1 summary?</p> <p>2 A. Yes. "In summary, we have</p> <p>3 demonstrated."</p> <p>4 Q. Okay. It says, and I'll read it</p> <p>5 into the record:</p> <p>6 "In summary, we have demonstrated a</p> <p>7 consistent association between talc and ovarian</p> <p>8 cancer that appears unlikely to be explained by</p> <p>9 recall and confounding."</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. So you talked about</p> <p>13 consistency, correct?</p> <p>14 MR. HEGARTY: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay.</p> <p>19 A. Yes.</p> <p>20 Q. You talked about whether or not it's</p> <p>21 explained by these other biases that counsel was</p> <p>22 asking about all day today, correct?</p> <p>23 MR. HEGARTY: Objection to the</p> <p>24 form.</p>

<p style="text-align: right;">Page 462</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay. You talked about, it says:</p> <p>4 "The dose-response relationship is</p> <p>5 weak but improved by considering factors such as</p> <p>6 closure of the female tract, ovulation and</p> <p>7 exposure prior to pregnancy, and we have outlined</p> <p>8 a plausible biologic rationale for this</p> <p>9 association."</p> <p>10 Do you see that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. That's exactly the same kinds of</p> <p>13 things you talked about in your litigation report,</p> <p>14 correct?</p> <p>15 MR. HEGARTY: Objection to the</p> <p>16 form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. It says:</p> <p>20 "We estimate that avoidance of talc</p> <p>21 in genital hygiene might reduce the occurrence of</p> <p>22 a highly lethal form of cancer by at least 10%."</p> <p>23 Correct?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 464</p> <p>1 anybody about your opinions about the biologic</p> <p>2 plausibility of talc, about the potential for talc</p> <p>3 reaching the ovaries, about the potential for</p> <p>4 asbestos contamination, that women ought to be</p> <p>5 told about -- about the risk or told to avoid the</p> <p>6 risk, you wrote that all in the 1990s.</p> <p>7 Correct?</p> <p>8 A. Yes.</p> <p>9 MR. HEGARTY: Objection to the</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. That was before you were ever</p> <p>13 contacted by any lawyers in this litigation, true?</p> <p>14 MR. HEGARTY: Object.</p> <p>15 BY MR. TISI:</p> <p>16 Q. By decades?</p> <p>17 A. Correct.</p> <p>18 Q. True?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. TISI:</p> <p>23 Q. All right. Let's move on.</p> <p>24 Counsel asked you some questions</p>
<p style="text-align: right;">Page 463</p> <p>1 MR. HEGARTY: Objection to the</p> <p>2 form.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. And that's something that was</p> <p>5 published in the peer-reviewed literature,</p> <p>6 correct?</p> <p>7 MR. HEGARTY: Objection to the</p> <p>8 form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. It says:</p> <p>12 "Balanced against what are primarily</p> <p>13 aesthetic reasons for using talc as genital</p> <p>14 hygiene, the risk benefit decision is not complex.</p> <p>15 Appropriate warnings should be provided to women</p> <p>16 about the potential risks of regular use in the</p> <p>17 genital area."</p> <p>18 Do you see that?</p> <p>19 MR. HEGARTY: Objection to the</p> <p>20 form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Okay. So when counsel asked you</p> <p>24 whether or not you had ever made -- ever told</p>	<p style="text-align: right;">Page 465</p> <p>1 about your letter to the editor.</p> <p>2 Okay. Now, this would have been</p> <p>3 after you had done some consulting with -- for --</p> <p>4 not made as an expert but was a consultant for</p> <p>5 talc litigants, correct?</p> <p>6 MR. HEGARTY: Objection to the</p> <p>7 form.</p> <p>8 THE WITNESS: That is</p> <p>9 correct.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. You told people -- you told</p> <p>12 the world that you had been a consultant in</p> <p>13 litigation, correct?</p> <p>14 MR. HEGARTY: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: I believe I</p> <p>17 said I -- well, I believe I --</p> <p>18 MR. HEGARTY: Misstates what</p> <p>19 he says.</p> <p>20 THE WITNESS: I specifically</p> <p>21 said that Dr. Harlow reported publishing</p> <p>22 research and serving as consultant on the</p> <p>23 topic of talc and ovarian cancer risk.</p> <p>24 BY MR. TISI:</p>

<p style="text-align: right;">Page 466</p> <p>1 Q. Okay. Now, Dr. Rothman. We've  2 talked about Dr. Rothman's report.  3 Do you know if Dr. Rothman actually  4 did a report for the talc industry?  5 MR. HEGARTY: Objection to  6 form.  7 THE WITNESS: At the time  8 that I wrote this letter?  9 BY MR. TISI:  10 Q. Yes.  11 A. I did not know that.  12 Q. Have you subsequently learned that?  13 A. Yes.  14 Q. Okay. The report that counsel asked  15 you about was done at the request of the Cosmetic  16 Toiletry Products -- I forget the acronym of it --  17 and was sponsored by Johnson &amp; Johnson, true?  18 MR. HEGARTY: Objection to  19 form. Lacks foundation. Also misstates  20 the facts. Calls for speculation.  21 BY MR. TISI:  22 Q. Have you learned that that was --  23 that was performed at the request of the talc  24 industry?</p>	<p style="text-align: right;">Page 468</p> <p>1 is that there was no biologic plausibility or he  2 had concerns about biologic plausibility.  3 Do you remember that testimony?  4 A. Yes.  5 MR. HEGARTY: Objection to the  6 form.  7 BY MR. TISI:  8 Q. All right. Is there any evidence  9 here that the -- that Dr. Rothman was told that  10 there were tests performed by Johnson &amp; Johnson in  11 the 1970s and 1980s which showed asbestos in talc?  12 MR. HEGARTY: Objection to  13 form.  14 THE WITNESS: I didn't see  15 any of that.  16 MR. HEGARTY: Lacks  17 foundation. Misstates the facts.  18 BY MR. TISI:  19 Q. Could you go to --  20 A. I didn't see it in the report.  21 Q. Could you go to Section B of your  22 expert report, please? I mean, Footnote B of your  23 expert report?  24 A. Okay. Okay. Footnote A. Footnote</p>
<p style="text-align: right;">Page 467</p> <p>1 A. Yes.  2 Q. Okay.  3 A. That is -- that is my understanding  4 of that report.  5 Q. Now, you have been asked about that,  6 and I can certainly show you what Dr. Rothman  7 said, but counsel selectively asked you questions  8 about Dr. Rothman's report, but I'm going to ask  9 you about it.  10 A. Okay.  11 Q. First of all, here is Exhibit Number  12 P7, I believe.  13 A. This goes to you.  14 MR. TISI: Is it P7?  15 MR. HEGARTY: That's what I  16 have.  17 MR. TISI: P7.  18 (Document marked for  19 identification as Exhibit P7.)  20 BY MR. TISI:  21 Q. Here you go.  22 Now, first of all, is there any  23 evidence that the talc industry told Dr. Rothman  24 that there was -- one of the things he says here</p>	<p style="text-align: right;">Page 469</p> <p>1 B. Yes.  2 Q. Okay. In Footnote B --  3 A. This is the William Longo?  4 Q. Right.  5 A. Okay.  6 Q. But there's also a reference to a  7 Hopkins exhibit.  8 Do you see that?  9 A. Yes.  10 Q. Okay. And do you recall counsel  11 asked you questions about -- about references to  12 asbestos in talc, and you mentioned Dr. Longo, and  13 he asked you all the questions about him being an  14 expert for plaintiffs and all that? All that?  15 A. (Nods head).  16 Q. Okay. You remember the Hopkins  17 exhibit was produced by J&amp;J's witness, correct?  18 MR. HEGARTY: Objection to the  19 form. Lacks foundation. Calls for  20 speculation.  21 THE WITNESS: I don't know  22 who. I don't know who. I don't know  23 whose --  24 BY MR. TISI:</p>

<p style="text-align: right;">Page 470</p> <p>1 Q. Okay.</p> <p>2 A. -- who put that forward.</p> <p>3 Q. Okay. I'm going to represent to you</p> <p>4 that there is evidence in this case that -- that</p> <p>5 William Hopkins was one of the people at the -- at</p> <p>6 the IS RTP meeting in 1995 and was a J&amp;J employee</p> <p>7 testified to test results that showed asbestos in</p> <p>8 talc. I'll represent to you that.</p> <p>9 Did you see any reference to that in</p> <p>10 Dr. Rothman's report when he was asked to do</p> <p>11 something, file this report by the talc industry?</p> <p>12 A. I didn't.</p> <p>13 MR. HEGARTY: Objection to the</p> <p>14 form.</p> <p>15 THE WITNESS: I did not.</p> <p>16 MR. HEGARTY: Counsel, did you</p> <p>17 say that Dr. Hopkins prepared Exhibit</p> <p>18 Number 28?</p> <p>19 MR. TISI: Oh, yeah, he did.</p> <p>20 I sure did.</p> <p>21 MR. HEGARTY: I would disagree</p> <p>22 with that.</p> <p>23 MR. TISI: Okay.</p> <p>24 MR. HEGARTY: It was a</p>	<p style="text-align: right;">Page 472</p> <p>1 dose response?</p> <p>2 A. I do.</p> <p>3 Q. Okay. And that would have been</p> <p>4 based on your study?</p> <p>5 MR. HEGARTY: Objection to the</p> <p>6 form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Okay. Now, Dr. Rothman's report was</p> <p>10 written in 2000, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. When he wrote his report with</p> <p>13 you in 2023, in the 23 years that had passed</p> <p>14 between his report and the time that you -- that</p> <p>15 you issued your report, you and he both noted that</p> <p>16 over time there was evidence of a dose response</p> <p>17 when considered against the backdrop of exposure,</p> <p>18 true?</p> <p>19 MR. HEGARTY: Objection to the</p> <p>20 form.</p> <p>21 THE WITNESS: We reported</p> <p>22 that.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Right.</p>
<p style="text-align: right;">Page 471</p> <p>1 plaintiffs' lawyer prepared document.</p> <p>2 MR. TISI: With -- with</p> <p>3 Dr. Hopkins giving testimony at the time.</p> <p>4 MR. HEGARTY: But you're</p> <p>5 telling -- you were telling Dr. Harlow --</p> <p>6 MR. TISI: At the deposition.</p> <p>7 MR. HEGARTY: -- that</p> <p>8 Dr. Hopkins prepared Exhibit 28.</p> <p>9 MR. TISI: Okay. Fine. We</p> <p>10 can disagree about the characterization.</p> <p>11 He prepared it at a deposition</p> <p>12 under oath with -- with -- with the</p> <p>13 attorney asking him questions about the</p> <p>14 test results.</p> <p>15 But let's go -- let's go</p> <p>16 through -- let's go through this.</p> <p>17 BY MR. TISI:</p> <p>18 Q. It talks about a dose response.</p> <p>19 A. Are we going back to Dr. Rothman's</p> <p>20 report?</p> <p>21 Q. Correct.</p> <p>22 A. Okay.</p> <p>23 Q. Do you believe that there was</p> <p>24 evidence at the time of Dr. Rothman's report of a</p>	<p style="text-align: right;">Page 473</p> <p>1 And that's not unusual in science</p> <p>2 where evidence accumulates over time and becomes</p> <p>3 more or less persuasive, ,correct?</p> <p>4 MR. HEGARTY: Objection to the</p> <p>5 form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. All right. Going back to the</p> <p>9 letter to the editor that you wrote.</p> <p>10 You were asked some questions about</p> <p>11 and even some, I would call, insulting questions</p> <p>12 about the statistically unsophisticated conclusion</p> <p>13 that -- that was reached about patent tubes.</p> <p>14 Do you remember that?</p> <p>15 MR. HEGARTY: Objection to the</p> <p>16 form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. First of all, you've --</p> <p>20 you've written a lot in the epidemiology</p> <p>21 literature.</p> <p>22 You've never heard of Dr. Gossett or</p> <p>23 Dr. del Carmen, have you?</p> <p>24 A. No.</p>

<p style="text-align: right;">Page 474</p> <p>1 MR. HEGARTY: Objection to the  2 form.  3 BY MR. TISI:  4 Q. Have you ever seen their name come  5 up in any of the talc literature that you  6 reviewed?  7 A. No.  8 Q. Okay. I'm going to refer you to  9 what Dr. -- putting aside what you and Dr. Rothman  10 wrote, I want to ask you about what Dr. -- how  11 Dr. O'Brien characterized her own study. Okay?  12 Look at Exhibit Number -- did we  13 mark this?  14 A. Are we talking about the letter to  15 the editor?  16 MR. HEGARTY: We did mark it.  17 BY MR. TISI:  18 Q. Actually, I'll just -- you have it  19 in front of you, don't you?  20 A. I do.  21 MR. TISI: I'll give you my  22 copy.  23 MR. HEGARTY: Okay.  24 MR. TISI: I'll give you my</p>	<p style="text-align: right;">Page 476</p> <p>1 And although we don't know  2 whether or not the association in  3 case-control study are true, in many  4 times case-control studies can  5 overestimate the association, but it  6 certainly seems like they are, as we  7 indicated, quite comparable.  8 And I believe that's what  9 she's suggesting here.  10 BY MR. TISI:  11 Q. Okay. And particularly with women  12 with patent tubes, correct?  13 MR. HEGARTY: Objection to the  14 form.  15 THE WITNESS: Well, in the  16 next -- in the next paragraph,  17 Dr. O'Brien specifically says:  18 "We completely agree with  19 Dr. Harlow and colleagues that our  20 results, particularly the analyses  21 limited to women with intact reproductive  22 tracts, should not be discounted because  23 of lack of statistical significance."  24 BY MR. TISI:</p>
<p style="text-align: right;">Page 475</p> <p>1 copy. You can look at it. We have it  2 previously marked.  3 BY MR. TISI:  4 Q. Do you see where Dr. -- if I could  5 come around the table and look at you.  6 Do you see where Dr. O'Brien writes:  7 "If cohort studies pooled HR 1.8 are  8 likely biased towards the null in case-control  9 studies are likely biased away from the null the  10 true association may be somewhere in the middle.  11 Do you see that?  12 A. I do.  13 Q. Does Dr. -- how do you interpret  14 what Dr. O'Brien says about the relevancy of her  15 study in either proving or disproving an  16 association between talc and ovarian cancer?  17 MR. HEGARTY: Objection to the  18 form.  19 THE WITNESS: She's saying  20 exactly what we have indicated in that  21 the -- because of the limitations on the  22 exposure assessment in the cohort  23 studies, we believe those estimates are  24 attenuated.</p>	<p style="text-align: right;">Page 477</p> <p>1 Q. Okay. Let me show you something  2 else that Dr. O'Brien said subsequent to the  3 publication of the article.  4 I'm going to show you an article I'm  5 going to have marked as Exhibit Number -- what  6 exhibit number are we at now?  7 MR. HEGARTY: P8.  8 MR. TISI: P8.  9 MR. HEGARTY: That's what I  10 have.  11 (Document marked for  12 identification as Exhibit P8.)  13 BY MR. TISI:  14 Q. This is an article from 2023,  15 December. So this would have been after your  16 expert report, correct?  17 A. Yes, because I did not see this at  18 the time I was doing the review.  19 Q. You saw that in connection with your  20 preparation for this deposition today, correct?  21 A. That's correct.  22 Q. And one of the things she says --  23 and this article is entitled "Association of  24 genital talc and douche use in early adolescence</p>



<p style="text-align: right;">Page 478</p> <p>1 or adulthood with uterine fibroids diagnoses."</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And she talks about -- she</p> <p>5 says on the right-hand side:</p> <p>6 "Talc is a poorly soluble particle,</p> <p>7 and animal models have shown that once deposited</p> <p>8 onto epithelial cells, it can cause chronic</p> <p>9 inflammation, leading to a series of mutagenic</p> <p>10 events, and this effect is worse in talc</p> <p>11 contaminated with asbestos, a known carcinogen."</p> <p>12 Correct?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: That is</p> <p>16 correct. And what's interesting is she's</p> <p>17 citing an article from 2015 and an</p> <p>18 article from 2019.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay.</p> <p>21 A. So this isn't new information.</p> <p>22 Q. All right. My point is: When you</p> <p>23 talk about -- to the extent that counsel is</p> <p>24 vouching for Dr. O'Brien's conclusions, one of the</p>	<p style="text-align: right;">Page 480</p> <p>1 BY MR. TISI:</p> <p>2 Q. I meant to say EPA. Environmental</p> <p>3 Protection Agency.</p> <p>4 A. I'm sorry. I thought I heard EPA.</p> <p>5 Q. Now, when you were asked questions,</p> <p>6 do you know of any governmental agency that ever</p> <p>7 concluded that talc-containing asbestos can cause</p> <p>8 ovarian cancer?</p> <p>9 Do you remember those questions?</p> <p>10 A. Yes.</p> <p>11 MR. HEGARTY: Objection to the</p> <p>12 form.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. And are you aware that the</p> <p>15 United States Environmental Protection Agency</p> <p>16 included just that very same thing?</p> <p>17 MR. HEGARTY: I'm going to</p> <p>18 object to the form. They did not say</p> <p>19 that talc use causes ovarian cancer.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Talc-containing asbestos causes</p> <p>22 ovarian cancer?</p> <p>23 MR. HEGARTY: Well, I didn't</p> <p>24 -- are you representing that's that what</p>
<p style="text-align: right;">Page 479</p> <p>1 things she talks about is the exact same biologic</p> <p>2 plausible mechanism you and Dr. Rothman talked</p> <p>3 about in your 2023 expert report, correct?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: That's correct.</p> <p>7 BY MR. TISI:</p> <p>8 Q. And, in fact, it's the same kind of</p> <p>9 biologic plausibility you talked about in the</p> <p>10 1990s and published in the peer-reviewed medical</p> <p>11 literature, true?</p> <p>12 A. Yes.</p> <p>13 MR. HEGARTY: Objection to the</p> <p>14 form.</p> <p>15 BY MR. TISI:</p> <p>16 Q. All right. Now, by the way, talking</p> <p>17 about things that are subsequent to your expert</p> <p>18 report.</p> <p>19 Do you understand that the FDA has</p> <p>20 come out with a -- with a final rule with respect</p> <p>21 to -- with respect to asbestos and, among other</p> <p>22 things, ovarian cancer?</p> <p>23 A. Yes.</p> <p>24 MR. HEGARTY: Did you say FDA?</p>	<p style="text-align: right;">Page 481</p> <p>1 that document says?</p> <p>2 MR. TISI: I'm going to</p> <p>3 show -- I'm going to show him what it</p> <p>4 says.</p> <p>5 MR. HEGARTY: All right.</p> <p>6 THE WITNESS: I know that</p> <p>7 there have been recent -- recent</p> <p>8 publications or recent documents that say</p> <p>9 that asbestos causes ovarian cancer was</p> <p>10 recent.</p> <p>11 BY MR. TISI:</p> <p>12 Q. And they also say that talc can</p> <p>13 contain asbestos -- asbestos, correct?</p> <p>14 MR. HEGARTY: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: I -- if you</p> <p>17 show it to me, I will agree.</p> <p>18 BY MR. TISI:</p> <p>19 Q. In fact, in Section B -- I will show</p> <p>20 you this in a minute.</p> <p>21 A. Yeah.</p> <p>22 Q. In Footnote B of your expert report,</p> <p>23 you refer to FDA testing of Johnson &amp; Johnson's</p> <p>24 talc, correct?</p>

<p style="text-align: right;">Page 482</p> <p>1 A. That's correct.</p> <p>2 Q. And what did they find?</p> <p>3 A. They found contamination.</p> <p>4 MR. HEGARTY: Objection to the</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay.</p> <p>8 A. They found contamination.</p> <p>9 MR. TISI: Let me mark as</p> <p>10 Exhibit Number 9.</p> <p>11 THE COURT REPORTER: 9.</p> <p>12 MR. TISI: Thank you for</p> <p>13 keeping track for me. I'm trying to move</p> <p>14 quickly.</p> <p>15 THE WITNESS: This is 7. Oh,</p> <p>16 no. Wait a minute.</p> <p>17 MR. TISI: That's 8. This</p> <p>18 is 9.</p> <p>19 THE WITNESS: Okay.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit P9.)</p> <p>22 MR. TISI: For the record,</p> <p>23 this is Federal Register dated March 28,</p> <p>24 2024.</p>	<p style="text-align: right;">Page 484</p> <p>1 Q. Going to the next page. Page --</p> <p>2 it's paginated at the top. I think it's the</p> <p>3 third -- fourth page in. 21973.</p> <p>4 A. Yes.</p> <p>5 Q. Middle paragraph, middle column.</p> <p>6 A. Yes.</p> <p>7 Q. Paragraph it says -- at the bottom</p> <p>8 it says:</p> <p>9 "Additionally, some" --</p> <p>10 A. Hold on. Let me find where it is.</p> <p>11 MR. HEGARTY: I'm not</p> <p>12 following where you are either.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MR. TISI: (Indicates).</p> <p>15 MR. HEGARTY: What's the</p> <p>16 heading on the section?</p> <p>17 MR. TISI: "Background."</p> <p>18 MR. HEGARTY: Okay. And</p> <p>19 you're talking about?</p> <p>20 MR. TISI: The middle,</p> <p>21 three-fourths down.</p> <p>22 MR. HEGARTY: Okay. Where the</p> <p>23 word starts "Additionally"?</p> <p>24 MR. TISI: "Additionally."</p>
<p style="text-align: right;">Page 483</p> <p>1 MR. HEGARTY: Do you have a</p> <p>2 copy for me?</p> <p>3 Can I have that clip that's in</p> <p>4 front of you? It's right there.</p> <p>5 MR. TISI: Yes.</p> <p>6 MR. HEGARTY: Thank you.</p> <p>7 BY MR. TISI:</p> <p>8 Q. First of all, do you see on the</p> <p>9 left-hand side it says --</p> <p>10 A. Under "Summary"?</p> <p>11 Q. Under "Summary," it says is issuing</p> <p>12 for --</p> <p>13 "The Environmental Protection Agency</p> <p>14 (EPA or the Agency) is issuing this final rule</p> <p>15 under the Toxic Substances Control Act to address</p> <p>16 to the extent necessary the unreasonable risk of</p> <p>17 injury to health presented by chrysotile asbestos</p> <p>18 based on the risks posed by certain conditions of</p> <p>19 use. The injuries to human health include."</p> <p>20 Could you tell us what they say?</p> <p>21 A. "The injuries to human health</p> <p>22 include mesothelioma and lung, ovarian, and</p> <p>23 laryngeal cancers resulting from chronic</p> <p>24 inhalation exposure to chrysotile asbestos."</p>	<p style="text-align: right;">Page 485</p> <p>1 THE WITNESS: Hold on. I'm</p> <p>2 looking for that. Can I see that again?</p> <p>3 BY MR. TISI:</p> <p>4 Q. Sure.</p> <p>5 A. I want to make sure that I'm</p> <p>6 following this.</p> <p>7 I got it. Okay. Uh-huh.</p> <p>8 Q. It says:</p> <p>9 "Additionally, some talc deposits</p> <p>10 and articles containing talc have been shown to</p> <p>11 contain asbestos. Thus, EPA recognizes that</p> <p>12 certain uses of talc may present the potential for</p> <p>13 asbestos exposure."</p> <p>14 Do you see that?</p> <p>15 A. I do.</p> <p>16 Q. Okay. And in fact, you were aware</p> <p>17 that the FDA did test Johnson &amp; Johnson's talc and</p> <p>18 did find talc in it, true?</p> <p>19 A. Yes.</p> <p>20 MR. HEGARTY: Objection to the</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. And one more question before I ask</p> <p>24 you the conclusion here.</p>

<p style="text-align: right;">Page 486</p> <p>1 It says --</p> <p>2 MR. HEGARTY: Where are you</p> <p>3 reading?</p> <p>4 BY MR. TISI:</p> <p>5 Q. On page 21975 under the title</p> <p>6 "Description of Unreasonable Risk."</p> <p>7 A. Uh-huh.</p> <p>8 Q. Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. It says -- and it talks about</p> <p>11 dose response. Three-quarters of the way down, it</p> <p>12 says:</p> <p>13 "Since there was no</p> <p>14 exposure-response data for ovarian and laryngeal</p> <p>15 cancer effects in the epidemiological literature,</p> <p>16 a direct estimate of risk from ovarian and</p> <p>17 laryngeal cancer could not be made for the</p> <p>18 inhalation unit risk calculation."</p> <p>19 A. Uh-huh.</p> <p>20 Q. It says:</p> <p>21 "An adjustment factor for ovarian</p> <p>22 and laryngeal cancer effects was applied to risk</p> <p>23 value estimates to correct for the underestimated</p> <p>24 total cancer risk derived from only lung cancer</p>	<p style="text-align: right;">Page 488</p> <p>1 you were asked some questions about inhalation --</p> <p>2 that this -- that this supports your opinion that</p> <p>3 that is an alternative plausible biologic</p> <p>4 mechanism for -- for the possibility of talc</p> <p>5 causing ovarian cancer?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: From</p> <p>9 inhalation, yes.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. And so whether or not</p> <p>12 asbestos is the cause of talc -- of talc causing</p> <p>13 ovarian cancer, it is a plausible -- is it a</p> <p>14 plausible mechanism?</p> <p>15 A. Yes.</p> <p>16 MR. HEGARTY: Objection to the</p> <p>17 form.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Is there evidence in the</p> <p>20 scientific and medical literature, including by</p> <p>21 this government agency, that would say that?</p> <p>22 A. Yes.</p> <p>23 MR. HEGARTY: Objection to the</p> <p>24 form.</p>
<p style="text-align: right;">Page 487</p> <p>1 and mesothelioma," it says.</p> <p>2 And then it goes on to say:</p> <p>3 "Total cancer risk encompassing all</p> <p>4 four cancers known to be caused by exposure to</p> <p>5 chrysotile asbestos."</p> <p>6 Do you see that?</p> <p>7 A. I do.</p> <p>8 Q. And if you go above, it says --</p> <p>9 right under the description, it says:</p> <p>10 "Unreasonable risk includes the risk</p> <p>11 of mesothelioma and lung, ovarian, and laryngeal</p> <p>12 cancers from chronic inhalation exposure."</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Let me ask you a couple</p> <p>15 questions about that.</p> <p>16 First of all, does this support your</p> <p>17 opinion that talc-containing asbestos is a</p> <p>18 biologically plausible mechanism for causing</p> <p>19 ovarian cancer?</p> <p>20 A. Yes.</p> <p>21 MR. HEGARTY: Objection to the</p> <p>22 form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Does it support your opinion -- and</p>	<p style="text-align: right;">Page 489</p> <p>1 BY MR. TISI:</p> <p>2 Q. In fact, that was also reported --</p> <p>3 was that also reported by IARC in 2012?</p> <p>4 A. Yes.</p> <p>5 MR. HEGARTY: Objection to the</p> <p>6 form.</p> <p>7 BY MR. TISI:</p> <p>8 Q. So when counsel says, does any</p> <p>9 federal -- does any governmental body ever say</p> <p>10 that talc can cause ovarian cancer, we have two</p> <p>11 agencies, including IARC and -- and the</p> <p>12 Environmental Protection Agency, saying talc with</p> <p>13 asbestos can cause ovarian cancer.</p> <p>14 Is that true or not true?</p> <p>15 MR. HEGARTY: Misstates the</p> <p>16 document.</p> <p>17 THE WITNESS: It is what they</p> <p>18 say.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. And, in fact, if you go one</p> <p>21 step further, Health Canada says they're not even</p> <p>22 looking at asbestos.</p> <p>23 They saw that talc as a whole,</p> <p>24 whatever is in the bottle, is a likely cause of</p>

<p style="text-align: right;">Page 490</p> <p>1 ovarian cancer, correct?</p> <p>2 MR. HEGARTY: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Now, did they -- unlike the FDA in</p> <p>7 the 2014 letter that you were shown before by the</p> <p>8 FDA --</p> <p>9 A. Uh-huh.</p> <p>10 Q. -- did Health Canada actually show</p> <p>11 its work?</p> <p>12 MR. HEGARTY: Objection to the</p> <p>13 form.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Did it list all the studies it</p> <p>17 considered?</p> <p>18 A. Yes, it did.</p> <p>19 Q. Did it go through the</p> <p>20 Bradford-Hill -- the Bradford considerations and</p> <p>21 talked about dose response and talk about biologic</p> <p>22 plausibility and all of those things, correct?</p> <p>23 A. Yes.</p> <p>24 MR. HEGARTY: Objection to the</p>	<p style="text-align: right;">Page 492</p> <p>1 MR. HEGARTY: And I need to do</p> <p>2 so before the flight leaves.</p> <p>3 MR. TISI: I'm just going to</p> <p>4 ask very short. I'm going to just -- and</p> <p>5 I need a break. Just one area that I</p> <p>6 know I have to -- I know I have to talk</p> <p>7 about here. Probably about -- Michelle,</p> <p>8 do you -- I have about five minutes, 10</p> <p>9 minutes.</p> <p>10 MR. HEGARTY: Okay.</p> <p>11 MS. PARFITT: 7:02. What time</p> <p>12 is your flight?</p> <p>13 MR. HEGARTY: 8:15. So I'm</p> <p>14 going to call. I have to change before</p> <p>15 it takes off.</p> <p>16 MS. PARFITT: You won't make</p> <p>17 it, Mark.</p> <p>18 MR. HEGARTY: No, I know. I'm</p> <p>19 not going to try to make it. I'm just</p> <p>20 saying I have to call.</p> <p>21 MS. PARFITT: Yeah, why don't</p> <p>22 we take a quick break.</p> <p>23 MR. TISI: Oh, yeah. We can</p> <p>24 do that.</p>
<p style="text-align: right;">Page 491</p> <p>1 form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Do you know from reading that</p> <p>4 document -- we can take it out, but I'm trying to</p> <p>5 be respectful of the time here.</p> <p>6 Do you know -- you said it was</p> <p>7 peer-reviewed.</p> <p>8 Do you know whether or not J&amp;J</p> <p>9 actually -- have you been informed that J&amp;J</p> <p>10 actually met with Health Canada and actually</p> <p>11 provided not only plaintiffs' expert reports in</p> <p>12 litigation, but also defendants' expert reports in</p> <p>13 litigation?</p> <p>14 A. I did not know that.</p> <p>15 MR. HEGARTY: Objection to the</p> <p>16 form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay. Now, let's talk a bit about</p> <p>19 dose response.</p> <p>20 MR. HEGARTY: Let me interrupt</p> <p>21 for just a second. How much longer are</p> <p>22 you going to go? I have to call to</p> <p>23 change my flight.</p> <p>24 MR. TISI: Well --</p>	<p style="text-align: right;">Page 493</p> <p>1 MR. HEGARTY: I have to call</p> <p>2 and reschedule before it takes off.</p> <p>3 (Recess: 7:02 p.m. -</p> <p>4 7:34 p.m.)</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm going to try to do this in a</p> <p>7 really summary way because it's late.</p> <p>8 A. (Nods head).</p> <p>9 Q. If you would go -- you remember the</p> <p>10 discussion of the PDQ?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And you remember the</p> <p>13 discussion about the question about whether or not</p> <p>14 there was inconsistency between O'Brien and the</p> <p>15 Woolen article.</p> <p>16 Do you remember that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. I'm happy to show you both of</p> <p>19 them.</p> <p>20 A. I have them in front of me.</p> <p>21 Q. Okay. But based upon your review of</p> <p>22 O'Brien, what did Woolen add -- what did Woolen</p> <p>23 look at that O'Brien did not, if anything?</p> <p>24 A. Well, I believe that Woolen was</p>

<p style="text-align: right;">Page 494</p> <p>1 trying to assess exposure in a more comprehensive  2 way.  3 Q. Okay.  4 A. I believe that's what they were  5 doing.  6 Q. Okay. And we're talking about  7 exposure, we're talking about -- to be clear,  8 we're talking about numbers of applications, which  9 is the thing that you have been concerned about  10 since the 1990s, correct?  11 A. That's correct.  12 Q. Okay. And to be simple about it,  13 it's number of years times number of applications,  14 correct?  15 MR. HEGARTY: Objection to the  16 form.  17 THE WITNESS: Taking into  18 account both years and applications is  19 the appropriate way to do it.  20 BY MR. TISI:  21 Q. Okay. Did she do that? Did  22 Woolen -- did the Woolen paper actually do that?  23 A. Well, I can't see exactly where they  24 did that.</p>	<p style="text-align: right;">Page 496</p> <p>1 using the O'Brien data.  2 BY MR. TISI:  3 Q. Okay. In what patient population?  4 A. The Nurses' Health Study.  5 Q. Okay. Was that the highest  6 exposure?  7 A. I believe it was.  8 Q. Okay. Okay. Did Woolen support --  9 does Woolen support your opinion that with  10 increasing -- increasing exposure comes increasing  11 risk?  12 A. It certainly confirms or supports  13 it, yes.  14 Q. Okay. Let me see. I do not think  15 that I have any other things, but let me just --  16 let me just take a quick look here.  17 Can you pull out the Taher article  18 that's Exhibit Number 26 since we're talking about  19 dose response.  20 A. Yeah, because the one I have in my  21 -- in my notebook is the wrong one. So do we have  22 that?  23 Q. Yeah, I have a copy of it.  24 A. Okay.</p>
<p style="text-align: right;">Page 495</p> <p>1 Q. Okay. So let me ask you this  2 question.  3 A. Yeah.  4 Q. There was the suggestion before, and  5 I want to be clear.  6 Is Woolen inconsistent with or did  7 it just look at different things than O'Brien?  8 A. Yeah. No.  9 MR. HEGARTY: Objection to  10 form.  11 THE WITNESS: No, I do not see  12 them as being substantially different.  13 BY MR. TISI:  14 Q. Okay.  15 A. Particularly when you look at the  16 confidence intervals.  17 Q. What did Woolen look at and what did  18 Woolen find?  19 A. Woolen found --  20 MR. HEGARTY: Objection to the  21 form.  22 THE WITNESS: Woolen found  23 overall association of 1.4 with a  24 confidence interval of 1.17 and 1.68</p>	<p style="text-align: right;">Page 497</p> <p>1 MR. TISI: Do you mind showing  2 him my copy? Actually, I think I have  3 it.  4 THE WITNESS: Because I  5 reviewed -- I reviewed the correct one,  6 but copied the wrong one.  7 (Discussion off the record)  8 THE WITNESS: Yeah, that's the  9 one.  10 BY MR. TISI:  11 Q. I'm going to ask you to look at  12 something different than on Michelle's copy, but  13 this is Exhibit Number 23.  14 A. Okay.  15 Q. I'll get you a clean one if you need  16 to but here is --  17 A. Or I can share it with you.  18 Q. I'm going to ask you to look at  19 table number -- this is Exhibit Number 23, but I'm  20 going to show you a clean copy of it.  21 If you would go to Table 3.  22 A. Oh, you have it. Okay.  23 Q. Do you see --  24 A. Right.</p>



<p style="text-align: right;">Page 498</p> <p>1 Q. -- there is a table?</p> <p>2 A. You mean the figure? (Indicates).</p> <p>3 Q. No, I mean the next page. Can I see</p> <p>4 it? I just want to make sure.</p> <p>5 A. (Indicates).</p> <p>6 Q. No, that's not the right one. I</p> <p>7 don't have my copy.</p> <p>8 Here it is. Table 2.</p> <p>9 A. Table 2. Uh-huh. Yes.</p> <p>10 Q. Okay. Do you see them break out, as</p> <p>11 you did, break out frequency of exposure?</p> <p>12 A. They have frequency of use, duration</p> <p>13 of use.</p> <p>14 Q. Okay. When they look at frequency</p> <p>15 greater than 10,000, do you see evidence of a dose</p> <p>16 response?</p> <p>17 A. No. No. The frequency is low,</p> <p>18 medium, high and duration is 10 years, 10 to 20</p> <p>19 years, 20 plus years.</p> <p>20 Q. Okay. Do you see when you look at</p> <p>21 those together, you see increasing -- increasing</p> <p>22 dose response?</p> <p>23 A. I don't --</p> <p>24 MR. HEGARTY: Objection to the</p>	<p style="text-align: right;">Page 500</p> <p>1 at.</p> <p>2 MR. TISI: Okay.</p> <p>3 FURTHER EXAMINATION</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Do you have the exhibits in front of</p> <p>6 you, Dr. Harlow, that Mr. Tisi asked you about?</p> <p>7 A. I have them. Yes, I guess they're</p> <p>8 right here. Okay.</p> <p>9 Q. The first study he asked you about</p> <p>10 was P1, "The association between douching, genital</p> <p>11 talc use, and the risk of prevalent and incident</p> <p>12 cervical cancer"?</p> <p>13 A. Yes.</p> <p>14 Q. You don't cite to this article in</p> <p>15 this body of your report, correct?</p> <p>16 A. No, I do not.</p> <p>17 Q. Did you find this article on your</p> <p>18 own?</p> <p>19 A. No.</p> <p>20 Q. Did plaintiffs' counsel provide it</p> <p>21 to you?</p> <p>22 A. They did.</p> <p>23 Q. Did you even reference this article</p> <p>24 in your list of references or Materials Considered</p>
<p style="text-align: right;">Page 499</p> <p>1 form.</p> <p>2 THE WITNESS: I don't see</p> <p>3 them put together.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Let me see. I'm not looking at the</p> <p>6 right one. Table 2, 3.2.</p> <p>7 MS. PARFITT: Table 2, Chris.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Actually, let me just -- let me</p> <p>10 just -- I don't have my copy. So I'm not going to</p> <p>11 do that.</p> <p>12 I have no other questions right now.</p> <p>13 Why don't we go through and let Mr. Hegarty ask</p> <p>14 his questions.</p> <p>15 (Recess: 7:41 p.m. -</p> <p>16 7:47 p.m.)</p> <p>17 MR. HEGARTY: At the outset, I</p> <p>18 just want to state an objection for the</p> <p>19 record, that is, to the extent</p> <p>20 Dr. Rothman -- I'm sorry -- Dr. Harlow</p> <p>21 was asked about or brought up opinions</p> <p>22 concerning studies or facts that were not</p> <p>23 previously disclosed in his expert</p> <p>24 report, and that's where I'll leave it</p>	<p style="text-align: right;">Page 501</p> <p>1 list, if you know?</p> <p>2 A. Yeah. No, I did not.</p> <p>3 MR. TISI: Well, it's in the</p> <p>4 Materials Considered list we provided</p> <p>5 you.</p> <p>6 MR. HEGARTY: And that's</p> <p>7 for -- is it in the box?</p> <p>8 MR. TISI: It's in the box.</p> <p>9 It's in the box.</p> <p>10 MR. HEGARTY: Okay.</p> <p>11 MR. TISI: May I have it?</p> <p>12 BY MR. HEGARTY:</p> <p>13 Q. Please turn over to page 2 of this</p> <p>14 article.</p> <p>15 A. Yes. Under what section?</p> <p>16 MR. TISI: Here.</p> <p>17 THE WITNESS: Okay.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. In the second -- I'm sorry. In the</p> <p>20 first full paragraph, second sentence, it reads:</p> <p>21 "Observational studies have</p> <p>22 documented associations between douching and HPV,</p> <p>23 cervical lesions or progression of cervical</p> <p>24 lesions from low to high grade. Additional,</p>

<p style="text-align: right;">Page 502</p> <p>1 several retrospective case-control studies have  2 reported positive association between douching and  3 cervical cancer. We did not identify any  4 prospective studies of relationship between  5 douching and cervical cancer. Such studies are  6 needed to rule out recall bias which can result  7 when an individual affected by a disease  8 over-report their exposure to an agent of  9 concern."  10 You agree with that statement, don't  11 you?  12 MR. TISI: Objection.  13 THE WITNESS: (Reviews  14 document.)  15 Well, again, you -- if it's  16 conducted appropriately and you can  17 actually identify those who were exposed  18 to douching and those who were not from  19 the beginning of their exposure  20 assessment, yes, then it would eliminate  21 recall bias.  22 BY MR. HEGARTY:  23 Q. What O'Brien and her coauthors are  24 saying here is that they looked at the</p>	<p style="text-align: right;">Page 504</p> <p>1 and ovarian cancer?  2 A. Well, for one thing, The Sister  3 Study excluded 160 cases, and so I don't have a  4 lot of confidence in their findings with respect  5 to talc and ovarian cancer.  6 Q. But did I properly summarize the  7 results of that Sister Study as published in the  8 Gonzalez paper?  9 A. Yes, there was -- there was an  10 associate between powder talc use and subsequent  11 ovarian cancer website. Douching was more common  12 among talc users, yes.  13 Oh, well. Douching was more common  14 among talc users and douching at baseline was  15 associated with increased subsequent risk of  16 ovarian cancer. Yes, that's what they said.  17 Q. With regard to the exposure data  18 that the Gonzalez study collected, it asked about  19 talc use in the prior 12 months, correct?  20 A. That's correct.  21 Q. If talc use is an habitual practice,  22 then talc use in the last 12 months would actually  23 reflect long-term talc use, correct?  24 A. Possibly, but, again, the problem is</p>
<p style="text-align: right;">Page 503</p> <p>1 case-control studies, but that prospective studies  2 are needed to rule out recall bias.  3 That's what that says, right?  4 A. That's what they're alluding to.  5 Q. Okay. Thank you.  6 Have you analyzed -- or let me start  7 over.  8 Have you done a comprehensive  9 analysis of the literature looking at douching as  10 a risk factor/cause for ovarian cancer?  11 A. I have not -- I have not done a  12 primary analysis around that, but I would have to  13 look in my previous studies to see whether I  14 looked at douching as a potential covariate.  15 Q. Do you consider douching as a risk  16 factor for ovarian cancer?  17 A. I have not done an extensive search  18 of the literature as to what it suggests there,  19 but I believe I was looking at douching as a  20 potential covariate.  21 Q. Do you recall that the Gonzalez  22 study concerning The Sister Study did find an  23 association statistically significant between  24 douching and ovarian cancer but not for talc use</p>	<p style="text-align: right;">Page 505</p> <p>1 is that these are women who are -- who were  2 followed forward in time who for whatever reason  3 had not developed ovarian cancer by the time they  4 were enrolled in this -- by the time they were  5 followed in this study. So what we call a  6 depletion of susceptibles, for whatever reason  7 they could very well have been resilient to the  8 development of ovarian cancer.  9 So I can't -- with that kind of  10 severe selection bias, I can't -- I can't really  11 put any stock in this -- in these findings,  12 particularly with respect to talc and ovarian  13 cancer.  14 Q. But my question was simply with  15 regard to identifying exposure of talc in the last  16 12 months.  17 A. If some --  18 Q. If it is a habitual habit, wouldn't  19 that indicate longer term use than simply in the  20 last 12 months?  21 A. Well, if it's just asking, have you  22 ever used it in the last 12 months, no, that would  23 not. But if you had used it in the last 12 months  24 every day applying it to the perineum, yes, to me,</p>

<p style="text-align: right;">Page 506</p> <p>1 that would suggest that they were probably using 2 it for longer periods of time. 3 Q. But if they had simply asked, have 4 you used talc in the last 12 months, it's your 5 opinion that that would not tell you anything 6 about long-term use before the last 12 months? 7 A. I wouldn't -- I would be hesitant to 8 make that assumption. 9 Q. Please turn to Plaintiff's 10 Exhibit 2, your study with Dr. Weiss. 11 A. Yes. 12 Q. That's entitled "A Case-Control 13 Study of Borderline Ovarian Tumors: The Influence 14 of Perineal Exposure to Talc." 15 A. Yes. 16 Q. Do you have that in front of you? 17 A. Yes, I do. 18 Q. In this study, you reported/found as 19 stated in the abstract that neither the perineal 20 application of baby powder nor the perineal 21 application of corn starch was associated with an 22 appreciable altered risk of borderline ovarian 23 tumors, correct? 24 A. That's what we found.</p>	<p style="text-align: right;">Page 508</p> <p>1 Q. Did you report in this study that 2 was marked as Exhibit P2 that women reported using 3 Shower to Shower? 4 A. I don't -- I'm trying to look to see 5 if we specifically stated that that was -- it was 6 asked. 7 (Reviews document.) 8 No, I did not report that. 9 Well, let me just quickly look in 10 the methods of the assessment of -- of it. 11 (Reviews document.) 12 "Baby powder, deodorizing powder, 13 and other unspecified talcum or dusting powders or 14 as corn starch." 15 So I cannot specifically say that 16 the deodorizing powder was talc-based, but if it 17 was corn starch, they would have said corn starch, 18 which we specifically asked that. 19 Q. In fact, if you look over in the 20 "Methods" section on page 2 -- 21 A. Yes. 22 Q. -- your open-ended question asked 23 women to specify the type but not the brand name, 24 correct?</p>
<p style="text-align: right;">Page 507</p> <p>1 Q. So you did not find an association 2 between talcum powder use and borderline tumors in 3 this study, correct? 4 A. Actually, that's not true. We found 5 an association with deodorizing powders and 6 ovarian cancer, and deodorizing powders are known 7 to be talc-based. 8 Q. The question, though, put to the 9 women in the study was not whether your 10 deodorizing powder contained talc, it was simply, 11 did you use deodorizing powder, correct? 12 A. That's correct. 13 Q. In the end, you don't know whether 14 the deodorizing powder that the women reported 15 using contained talc, right? 16 A. Well, many of them suggested or even 17 indicated that it was Shower to Shower, and I know 18 that Shower to Shower deodorizing powder does 19 contain talc. I don't know of deodorizing powders 20 other than corn starch, and we specifically asked 21 about corn starch, would other than -- other than 22 those that are specifically indicated as corn 23 starch, deodorizing powder I would make the 24 assumption was a talc-based product.</p>	<p style="text-align: right;">Page 509</p> <p>1 A. That is correct. 2 Q. So they would not in answering that 3 question have specified Shower to Shower, which is 4 a brand name product, correct? 5 A. We did not analyze that data. We 6 did collect that information, but it was not 7 considered reliable to be able to actually look at 8 it that way, and so that's the reason why we 9 analyzed it this way. 10 Q. In this study, you did not find that 11 perineal application of baby powder was associated 12 with an appreciable altered risk of borderline 13 ovarian tumors, correct? 14 A. That's correct. Except that 15 deodorizing powder in combination was associated 16 with risk. As you can see in Table 1, deodorizing 17 powder only was associated with 3.5 fold 18 association and deodorizing powder only or in 19 combination was associated with 2.8 fold 20 association. 21 Q. My question, though, was as specific 22 to baby powder. 23 A. That is correct. Baby powder. 24 Q. You did not find an association</p>

<p style="text-align: right;">Page 510</p> <p>1 between baby powder use and borderline ovarian  2 tumors, correct?  3 A. It -- yes.  4 Q. I believe you testified earlier, but  5 please correct me if I'm wrong, that you did not  6 do a separate analysis -- let me restart that.  7 Strike that.  8 Am I correct that you do not have an  9 opinion as to whether talcum powder use causes  10 borderline tumors?  11 A. I cannot make that assumption only  12 because I believe this may be the only study that  13 specifically focused on borderline ovarian tumors.  14 Q. Do you have an opinion as to whether  15 talcum powder use can cause endometrial cancer,  16 that is, cancer of the endometrium?  17 A. I have not reviewed that literature.  18 Q. Please turn to Exhibit Number 3.  19 That is P3. I'm sorry.  20 A. Right. Is that the 1992 article?  21 Q. Yes, Doctor. With regard to that  22 article, please turn to page 25.  23 This first, the last full paragraph  24 on the right-hand side, it reads:</p>	<p style="text-align: right;">Page 512</p> <p>1 Q. Next you say:  2 "Because our associations are based  3 upon responses from participating cases and  4 controls, the validity of our results depends upon  5 the assumption that respondents and  6 non-respondents were similar with respect to talc  7 and other relevant exposures, or that the  8 magnitude of any respondent-non-respondent  9 difference was similar for cases and controls.  10 Because the interview provided the only source of  11 'exposure' information, we were unable to assess  12 the likelihood of this assumption."  13 That's all accurate, correct?  14 A. That is correct. Because non --  15 because nondifferential misclassification would  16 drive the association towards the null, which  17 means that the associations we see are an  18 underestimate of the true association.  19 Q. You were also asked questions about  20 the IS RTP -- let me start over.  21 You were also asked questions about  22 the FDA workshop that you attended back in 1994,  23 correct?  24 A. Yes.</p>
<p style="text-align: right;">Page 511</p> <p>1 "Non-causal explanations are  2 possible in any epidemiologic research."  3 Is that a correct statement?  4 A. Yes.  5 Q. Okay. You go on to write:  6 "We cannot rule out the possibility  7 of differential over- or under-reporting of talc  8 exposure in our cases and controls, especially in  9 those with reproductive events that enhance odds  10 ratios."  11 Is that a correct statement?  12 A. That's what I said. That's correct,  13 yes.  14 Q. You go on to say:  15 "In addition, though we were  16 successful in interviewing 69% of eligible ovarian  17 cancer cases and 81% of eligible controls  18 contacted, we cannot assess whether the cases and  19 controls not interviewed could have selectively  20 differentiated -- could have selectively differed  21 in their reproductive characteristics or in their  22 use of talc-containing body powders."  23 That's a correct statement as well?  24 A. That's correct.</p>	<p style="text-align: right;">Page 513</p> <p>1 Q. Who invited you to that workshop?  2 A. I don't recall who actually sent me  3 the invitation. I was invited by whoever was  4 coordinating it.  5 MR. TISI: I'm sorry. That's  6 my sticky note on it, which is not  7 intended.  8 THE WITNESS: Sorry.  9 BY MR. HEGARTY:  10 Q. Please look at P4, the Carr 1995  11 paper that you talked about with --  12 A. Yes.  13 Q. -- counsel for plaintiffs and you  14 talked about with me.  15 A. Yes.  16 Q. You told counsel for plaintiffs that  17 you felt that the summary as reported by Mr. Carr  18 was not fair and balanced.  19 Is that what you believe?  20 A. I do believe that to be the case  21 with respect to the epidemiologic evidence.  22 Q. Have you ever said or made that  23 statement in any published peer-reviewed or  24 otherwise publication of yours?</p>

<p style="text-align: right;">Page 514</p> <p>1 A. I have not.</p> <p>2 Q. Have you ever made that statement to</p> <p>3 anyone outside of today's proceedings?</p> <p>4 A. I have not.</p> <p>5 Q. And as we talked, you never did a</p> <p>6 follow-up letter to the editor or other report</p> <p>7 where you commented on the summary that Carr</p> <p>8 provided in P4?</p> <p>9 MR. TISI: Objection.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Is that correct?</p> <p>12 MR. TISI: Objection.</p> <p>13 Misstates --</p> <p>14 THE WITNESS: I'd like --</p> <p>15 MR. TISI: Misstates what</p> <p>16 happened, but go ahead.</p> <p>17 THE WITNESS: Am I allowed to</p> <p>18 answer?</p> <p>19 MR. TISI: Yeah.</p> <p>20 THE WITNESS: The review that</p> <p>21 I did in the same issue was my response</p> <p>22 to that particular summary.</p> <p>23 BY MR. HEGARTY:</p> <p>24 Q. And that review, which is P5?</p>	<p style="text-align: right;">Page 516</p> <p>1 Q. Top left.</p> <p>2 A. Oh. "Because the risk"?</p> <p>3 Q. First full paragraph.</p> <p>4 A. Yep. Uh-huh.</p> <p>5 Q. "Because the risk of any one outcome</p> <p>6 is dependent upon both the frequency and length of</p> <p>7 the exposure, Harlow et al. (1992) created a</p> <p>8 continuous measure of total lifetime applications</p> <p>9 for each case and control."</p> <p>10 Do you remember talking to that with</p> <p>11 plaintiffs' counsel?</p> <p>12 A. Yes.</p> <p>13 Q. And then I believe you testified</p> <p>14 that what that meant was that reporting only on</p> <p>15 frequency or only on duration is a limitation when</p> <p>16 assessing essentially dose response.</p> <p>17 Is that a fair summary?</p> <p>18 A. I believe it is.</p> <p>19 Q. Do you have the Woolen paper in</p> <p>20 front of you? It's Exhibit 19.</p> <p>21 A. I do.</p> <p>22 Q. Or your copy of the Woolen paper?</p> <p>23 A. Yeah. Yeah. Yeah, I do.</p> <p>24 Woolen is right here. Got it.</p>
<p style="text-align: right;">Page 515</p> <p>1 A. Correct.</p> <p>2 Q. So you can look at P5.</p> <p>3 A. Yeah.</p> <p>4 Q. I should say: In that review, you</p> <p>5 did not make the statement that any summary of the</p> <p>6 proceedings was not fair and balanced, correct?</p> <p>7 A. I would not have done that in a</p> <p>8 peer-reviewed article.</p> <p>9 Q. You made the statement in response</p> <p>10 to plaintiffs' counsel --</p> <p>11 A. Are we still on this article or have</p> <p>12 you moved off?</p> <p>13 Q. Let me see. I'm looking at my --</p> <p>14 okay. Yeah. I'm sorry. Please stay with P5.</p> <p>15 Please turn over to 256, and this</p> <p>16 was a statement you talked about with counsel for</p> <p>17 plaintiff.</p> <p>18 A. Uh-huh.</p> <p>19 Q. The statement: "Because the risk of</p> <p>20 any" --</p> <p>21 A. Well, just remind me where exactly</p> <p>22 it is, please.</p> <p>23 Q. It is top left.</p> <p>24 A. Top left.</p>	<p style="text-align: right;">Page 517</p> <p>1 Q. Thank you.</p> <p>2 The Woolen paper reported only on</p> <p>3 frequency of use and risk of ovarian cancer,</p> <p>4 correct?</p> <p>5 A. Frequent use where they defined it</p> <p>6 as greater than 2 times per week.</p> <p>7 Q. So the only thing they reported with</p> <p>8 regard to duration or frequency was as to more</p> <p>9 than 2 times a week, correct?</p> <p>10 A. Yes, that's correct.</p> <p>11 Q. They did not report a combined</p> <p>12 cumulative exposure of dose of duration and</p> <p>13 frequency, correct?</p> <p>14 A. No.</p> <p>15 MR. TISI: Objection.</p> <p>16 Misstates.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. That would then be, according to</p> <p>19 your testimony just a moment ago, a limitation of</p> <p>20 what conclusions you can draw from the Woolen</p> <p>21 paper, correct?</p> <p>22 MR. TISI: Objection.</p> <p>23 THE WITNESS: Actually, no,</p> <p>24 that's not a limitation.</p>



<p style="text-align: right;">Page 518</p> <p>1 Yes, it's a limitation in that</p> <p>2 they did not look at a consecutive</p> <p>3 association between, you know, between</p> <p>4 increase and risk, but they did something</p> <p>5 that most studies had not been able to do</p> <p>6 and that's to really look at one -- at</p> <p>7 the papers that provided the best</p> <p>8 information on more frequent use, and</p> <p>9 that's why they included only those</p> <p>10 studies.</p> <p>11 That information available to</p> <p>12 them on greater than 2 times per week so</p> <p>13 that they could look at -- rather than</p> <p>14 just looking at any or none, they're now</p> <p>15 able to look at greater than 2 times per</p> <p>16 week versus none, and they see an</p> <p>17 association that's a bit stronger.</p> <p>18 BY MR. HEGARTY:</p> <p>19 Q. Woolen does not talk about duration</p> <p>20 of talc use, correct?</p> <p>21 A. Only to the extent that that's the</p> <p>22 way they chose to do this analysis by selecting</p> <p>23 those studies that had at least greater than 2</p> <p>24 times per week of exposure.</p>	<p style="text-align: right;">Page 520</p> <p>1 agree.</p> <p>2 Q. Okay.</p> <p>3 A. It should be disclosed.</p> <p>4 Q. And with regard to the Woolen --</p> <p>5 A. Wait. Except that I do want to just</p> <p>6 make -- make sure that you -- that it's clarified</p> <p>7 that the first author, Sean Woolen, has no</p> <p>8 relevant disclosures and Lazar, the second author,</p> <p>9 has no relevant disclosures. And usually the</p> <p>10 first author is the one that writes the paper and</p> <p>11 makes the ultimate decision on what is published.</p> <p>12 Q. Well, are you aware that the Woolen</p> <p>13 paper was started by Dr. Smith-Bindman as part of</p> <p>14 an expert witness report that she prepared in the</p> <p>15 Pennsylvania state court case called Kliner versus</p> <p>16 Johnson &amp; Johnson?</p> <p>17 MR. TISI: Objection.</p> <p>18 THE WITNESS: I'm not aware</p> <p>19 of that.</p> <p>20 BY MR. HEGARTY:</p> <p>21 Q. Would that be something important</p> <p>22 for you to know?</p> <p>23 MR. TISI: Objection.</p> <p>24 Misstates.</p>
<p style="text-align: right;">Page 519</p> <p>1 Q. Have you ever in any epidemiologic</p> <p>2 study of yours reported as to dose response only</p> <p>3 duration or only frequency?</p> <p>4 A. I'm sure I've done them</p> <p>5 individually, but also in combination when the</p> <p>6 data is available to me.</p> <p>7 Q. Are you aware that with regard to</p> <p>8 the Woolen paper that one of the authors,</p> <p>9 Dr. Smith-Bindman, is a plaintiffs' expert in this</p> <p>10 same litigation that you are?</p> <p>11 A. No.</p> <p>12 Q. Did you review her disclosure in</p> <p>13 this paper over on page 2532?</p> <p>14 A. I see that. Uh-huh.</p> <p>15 Q. Is that an appropriate disclosure if</p> <p>16 you're an expert witness in talc litigation for</p> <p>17 the plaintiffs?</p> <p>18 MR. TISI: Objection.</p> <p>19 THE WITNESS: I don't -- I</p> <p>20 think it's not unreasonable to declare</p> <p>21 that.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. It's not --</p> <p>24 A. In fact, I think they should. I</p>	<p style="text-align: right;">Page 521</p> <p>1 THE WITNESS: Only if this</p> <p>2 information had not been peer-reviewed in</p> <p>3 the scientific literature.</p> <p>4 BY MR. HEGARTY:</p> <p>5 Q. Please turn over to Table 2 in the</p> <p>6 Woolen paper.</p> <p>7 A. Yes. Table 2. Uh-huh.</p> <p>8 Q. With regard to the data that this</p> <p>9 Woolen paper combined, it included frequency data</p> <p>10 that was not consistent across all the studies,</p> <p>11 correct?</p> <p>12 A. That's correct. Well, yes, that's</p> <p>13 correct.</p> <p>14 Q. Then if you look down at the very</p> <p>15 bottom in Footnote 5, do you see with regard to</p> <p>16 the data from the O'Brien study that Dr. -- that</p> <p>17 the Woolen paper only included data on women with</p> <p>18 intact fallopian tubes?</p> <p>19 A. (Reviews document.)</p> <p>20 I do see that. Uh-huh. "To</p> <p>21 harmonize with other publications."</p> <p>22 Q. Have you looked at whether the other</p> <p>23 publications only reported data on women with</p> <p>24 intact fallopian tubes?</p>

<p style="text-align: right;">Page 522</p> <p>1 A. I have not.</p> <p>2 Q. It --</p> <p>3 A. You mean across all these other</p> <p>4 studies?</p> <p>5 Q. That's right.</p> <p>6 A. Yeah.</p> <p>7 Q. So to truly harmonize across all 11</p> <p>8 studies, all 11 studies would need to report their</p> <p>9 data only as to women with intact fallopian tubes,</p> <p>10 correct?</p> <p>11 MR. TISI: Objection.</p> <p>12 THE WITNESS: Well, I would</p> <p>13 have to look at these articles. So</p> <p>14 certainly I know that Cramer and Harlow</p> <p>15 would have that ability to provide to --</p> <p>16 to separate out that exposure.</p> <p>17 I would have to look back at</p> <p>18 the articles to see if all of these</p> <p>19 articles specifically allowed for that</p> <p>20 separation.</p> <p>21 BY MR. HEGARTY:</p> <p>22 Q. If they don't all allow for that</p> <p>23 separation, then there would not be harmonization</p> <p>24 across all the studies, correct?</p>	<p style="text-align: right;">Page 524</p> <p>1 ratios were above 1.</p> <p>2 Q. The only trend you found was what</p> <p>3 you reported at the end of that table; is that</p> <p>4 correct?</p> <p>5 A. Yes, that is -- that is the trend --</p> <p>6 that is -- that is a trend that we reported when</p> <p>7 we felt we adequately refined the exposure aligned</p> <p>8 with the biological plausibility that we were</p> <p>9 testing.</p> <p>10 Q. Please turn to the very last page</p> <p>11 that you were asked about by counsel for</p> <p>12 plaintiffs, particularly the very last sentence of</p> <p>13 this study.</p> <p>14 A. Of this article?</p> <p>15 Q. Yes, sir.</p> <p>16 A. Okay.</p> <p>17 Q. The sentence about "Appropriate</p> <p>18 warnings should be provided."</p> <p>19 Do you see that sentence?</p> <p>20 A. Yes.</p> <p>21 "Appropriate warnings should be</p> <p>22 provided to women about the potential risks of</p> <p>23 regular use of talc in the genital area."</p> <p>24 Q. As we looked at today and as you are</p>
<p style="text-align: right;">Page 523</p> <p>1 A. I -- I think that it would not be</p> <p>2 the same across all studies. That's right.</p> <p>3 Q. You can put that document aside.</p> <p>4 A. Okay.</p> <p>5 Q. And please look at P6.</p> <p>6 MR. TISI: How much time do we</p> <p>7 have? I mean, in light of the fact I did</p> <p>8 do longer, I'm giving you some leeway.</p> <p>9 But are we about to land the plane?</p> <p>10 MR. HEGARTY: That's my</p> <p>11 intent.</p> <p>12 MR. TISI: Okay.</p> <p>13 THE WITNESS: Okay. So P6.</p> <p>14 What am I looking at?</p> <p>15 BY MR. HEGARTY:</p> <p>16 Q. That is the 1999 study.</p> <p>17 A. Got it. Yep.</p> <p>18 Q. Turning over to Table III on page</p> <p>19 354.</p> <p>20 A. Yes.</p> <p>21 Q. You did not find in the middle part</p> <p>22 of that table a trend for years of use or total</p> <p>23 applications of use, correct?</p> <p>24 A. That is correct, but all of the odds</p>	<p style="text-align: right;">Page 525</p> <p>1 aware, FDA disagrees with that statement, correct?</p> <p>2 MR. TISI: Objection.</p> <p>3 Objection. Misstates the document.</p> <p>4 Misstates the document completely.</p> <p>5 BY MR. HEGARTY:</p> <p>6 Q. You can answer.</p> <p>7 A. Are you referring to the response to</p> <p>8 the -- to the committee? To the -- to the -- to</p> <p>9 the -- what was it? The -- the.</p> <p>10 Q. Citizens --</p> <p>11 A. Citizens Petition?</p> <p>12 Q. Yes.</p> <p>13 A. Is that what you're talking about?</p> <p>14 Q. I am.</p> <p>15 A. They -- they made a summary that</p> <p>16 they did not feel there was evidence to put a</p> <p>17 warning on or to recommend a warning on the</p> <p>18 product. That is what they said.</p> <p>19 Q. And you're aware from whatever</p> <p>20 sources of information that no talcum powder</p> <p>21 product in the United States -- let me start</p> <p>22 again.</p> <p>23 MR. TISI: Please.</p> <p>24 BY MR. HEGARTY:</p>

<p style="text-align: right;">Page 526</p> <p>1 Q. Are you aware that FDA has not  2 required an ovarian cancer warning on any talcum  3 powder product?  4 MR. TISI: Objection.  5 THE WITNESS: I am not aware  6 that they have.  7 BY MR. HEGARTY:  8 Q. You can put that document aside.  9 MR. TISI: I kind of feel like  10 the plane should be landing.  11 MR. HEGARTY: I'm simply --  12 I'm following up on things that you had  13 asked him.  14 MR. TISI: I understand that.  15 MS. PARFITT: Come on.  16 Denise, how long have we gone?  17 MR. HEGARTY: Well, if you  18 want to cut me off, then that's up to  19 you.  20 MR. TISI: Well, let me just  21 find out how much time we have.  22 MR. HEGARTY: Sure. Go ahead.  23 MR. TISI: It was about 15  24 minutes. I gave you leeway.</p>	<p style="text-align: right;">Page 528</p> <p>1 you'll give me, and then I will limit it  2 to that. That's all I can do.  3 MR. TISI: As long as you tell  4 your colleagues that I did.  5 MS. PARFITT: Give back. Give  6 back to us, Mark. Not everybody is --  7 MR. HEGARTY: Sure. So what  8 do you want? Just tell me what you're  9 going to give me.  10 MR. TISI: I'll give you five  11 minutes.  12 MR. HEGARTY: Okay. Give me  13 five minutes. Okay.  14 BY MR. HEGARTY:  15 Q. Looking at your conflict of interest  16 disclosure in your letter to the editor?  17 A. Yes.  18 Q. You did not make any reference in  19 that conflict of interest disclosure that the  20 consultation you were doing was in connection with  21 litigation?  22 MR. TISI: Objection.  23 Objection. Assumes facts. We went -- we  24 did go through this like in a lot of</p>
<p style="text-align: right;">Page 527</p> <p>1 MR. HEGARTY: Yeah.  2 MR. TISI: I told I was going  3 to do -- respond to your things. You  4 chose to reserve the amount of time that  5 you did. I'm trying to -- I'm trying to  6 be reasonable, but it is late.  7 How much time have we used?  8 THE COURT REPORTER: Let's  9 see. 13 and 14. 27 minutes.  10 MR. HEGARTY: Just tell me how  11 much you're going to give me, and then  12 I'll stick to it.  13 MR. TISI: Well, I mean,  14 you've doubled. I've given you double  15 the amount of time, and I've really tried  16 to be reasonable.  17 MR. HEGARTY: I agree with  18 you.  19 MR. TISI: How much time do  20 you have?  21 MR. HEGARTY: I will cut some  22 of this. I will -- just give me -- if  23 you want to give me five minutes, I'll  24 use five minutes. Just tell me whatever</p>	<p style="text-align: right;">Page 529</p> <p>1 detail earlier.  2 BY MR. HEGARTY:  3 Q. I'm just simply asking you to look  4 at the words of the disclosure itself and tell me  5 whether you made -- you reported in that  6 disclosure that the consultation work you did was  7 in connection with litigation.  8 MR. TISI: But he indicated he  9 didn't know he was going to be in  10 litigation.  11 THE WITNESS: No, no, no. It  12 was not -- it was -- my conflict is that  13 I was serving as a consultant on the  14 topic of talc and ovarian cancer risk.  15 It was I -- it was -- it may  16 or may not have resulted in litigation.  17 I don't know. I was not an expert  18 witness.  19 BY MR. HEGARTY:  20 Q. Your consultation, though, was with  21 attorneys representing plaintiffs?  22 A. That's correct.  23 Q. Okay. You were asked about Hopkins,  24 Exhibit Number 28.</p>

<p style="text-align: right;">Page 530</p> <p>1 Do you know the source of that</p> <p>2 exhibit?</p> <p>3 A. Oh, in my -- in my report.</p> <p>4 Q. In your report.</p> <p>5 A. Yeah. No, other than the reference</p> <p>6 that I provided.</p> <p>7 This is -- this is Footnote B,</p> <p>8 correct?</p> <p>9 MR. TISI: Yes.</p> <p>10 BY MR. HEGARTY:</p> <p>11 Q. Yes.</p> <p>12 A. Yeah.</p> <p>13 (Reviews document.)</p> <p>14 Yeah. Yeah. And I recognize that</p> <p>15 it was an exhibit from a deposition.</p> <p>16 Q. You were asked about -- final set of</p> <p>17 questions.</p> <p>18 You were asked about Exhibit P9,</p> <p>19 correct?</p> <p>20 A. Yes, the EPA report.</p> <p>21 Q. And when did you review this exhibit</p> <p>22 for the first time?</p> <p>23 A. I just saw it a few -- I think -- I</p> <p>24 think I might have seen it Friday.</p>	<p style="text-align: right;">Page 532</p> <p>1 whether that information might be</p> <p>2 available if I wanted to see it.</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. But as far as your review of this,</p> <p>5 with regard to your review of this document, you</p> <p>6 did not see any of the authorities that the EPA</p> <p>7 relied upon, correct?</p> <p>8 A. I did not.</p> <p>9 Q. You told me earlier in the day that</p> <p>10 one of the standards for which you applied in your</p> <p>11 report as to whether you would comment on an</p> <p>12 analysis in your paper was they had to show you</p> <p>13 the analysis that they did, correct?</p> <p>14 A. That is correct but --</p> <p>15 MR. TISI: Objection.</p> <p>16 THE WITNESS: But --</p> <p>17 MR. TISI: This is for a</p> <p>18 different reason. Now, go ahead.</p> <p>19 BY MR. HEGARTY:</p> <p>20 Q. And then --</p> <p>21 MR. TISI: He testified on a</p> <p>22 causal analysis. This is just biologic</p> <p>23 plausibility. I mean, he testified to</p> <p>24 that.</p>
<p style="text-align: right;">Page 531</p> <p>1 Q. Was that provided to you by</p> <p>2 plaintiffs' counsel?</p> <p>3 A. Yes, it was.</p> <p>4 Q. Did you make a request for it</p> <p>5 initially?</p> <p>6 A. No, I did not.</p> <p>7 Q. You have reviewed this document,</p> <p>8 correct?</p> <p>9 A. I haven't reviewed every bit of the</p> <p>10 page, but I've reviewed the summaries on it.</p> <p>11 Q. Nowhere in this document does EPA</p> <p>12 cite to any published or otherwise literature that</p> <p>13 it reviewed with regard to its statements as it</p> <p>14 relates to asbestos and ovarian cancer or talc and</p> <p>15 ovarian cancer, correct?</p> <p>16 MR. TISI: Objection.</p> <p>17 THE WITNESS: Yeah. I -- I</p> <p>18 don't -- well, I'd have to look to see if</p> <p>19 they provided a citation on this report,</p> <p>20 but things that come out of the Federal</p> <p>21 Register are -- do not typically have</p> <p>22 those kinds of references.</p> <p>23 Oh, no, like -- yeah. I don't</p> <p>24 know whether if I went to the EPA site</p>	<p style="text-align: right;">Page 533</p> <p>1 BY MR. HEGARTY:</p> <p>2 Q. Please answer. I think you were</p> <p>3 starting to answer my question. Go ahead.</p> <p>4 A. I was going to answer that the</p> <p>5 response to the citizen committee was not</p> <p>6 something that came out in the Federal Register</p> <p>7 for public observation to make a position stance</p> <p>8 on the part of the FDA.</p> <p>9 It was my understanding in response</p> <p>10 to a petition as to whether they would approve the</p> <p>11 labeling of -- of risk of talc on a cosmetic talc</p> <p>12 product.</p> <p>13 This is in the Federal Register.</p> <p>14 (Indicates). This is a mandate essentially, in my</p> <p>15 view, from the EPA and I -- it feels different to</p> <p>16 me.</p> <p>17 Q. So --</p> <p>18 A. This feels different to me.</p> <p>19 Q. So with regard to P9, this would be</p> <p>20 an authority you would feel would meet your</p> <p>21 methodology standards for including a discussion</p> <p>22 about it in your report; is that correct?</p> <p>23 MS. PARFITT: Objection.</p> <p>24 THE WITNESS: This is -- this</p>

<p style="text-align: right;">Page 534</p> <p>1 is what appears to me is a mandate that 2 has been put forward by a federal agency. 3 It is different from what I saw in that 4 FDA response to a citizens committee. 5 I would hope that a mandate 6 such as this would be backed by evidence, 7 and given that it says it's its final 8 rule, I would assume that there were -- 9 there were iterative processes that it 10 went through in order to be able to come 11 up with these -- this summary. 12 BY MR. HEGARTY: 13 Q. Going back to my question. 14 Would it meet your standard that you 15 applied for preparing your report -- 16 A. If there was no -- 17 Q. -- to include an analysis in your 18 report? 19 A. Yeah. If there was no background 20 information that I could find to support this, 21 then it would not meet my standard. 22 MR. HEGARTY: Okay. All 23 right. Given the time that I've been 24 allowed, those are all the questions that</p>	<p style="text-align: right;">Page 536</p> <p>1 agency or scientific authority had said 2 that talc use causes ovarian cancer. 3 MR. TISI: With asbestos. 4 MR. HEGARTY: I did not ask 5 that question. The record will speak for 6 itself. 7 MR. TISI: Right. 8 MR. HEGARTY: And will not 9 reach agreement I'm sure today on our 10 objections or your response. So -- 11 MR. TISI: I understand. 12 MR. HEGARTY: -- I guess that 13 will be it. 14 MR. TISI: Thank you. 15 16 (Signature not waived, the 17 deposition concluded at 8:21 p.m.) 18 19 * * * 20 21 22 23 24</p>
<p style="text-align: right;">Page 535</p> <p>1 I have. 2 I'll reiterate my objection to 3 the extent that Dr. Harlow was asked 4 about a question about materials that 5 have not previously been disclosed that 6 he would include as a basis for his 7 opinions, that we reserve the right to 8 seek additional time to the extent 9 warranted. 10 MR. TISI: We, obviously, 11 object to that. I've given you more than 12 enough time. All the documents that you 13 have were in the Dropbox. We provided 14 them several days in advance. These are 15 not new opinions. 16 These are documents that came 17 out recently and we further support the 18 opinions that you already have. And you 19 asked him whether or not any particular 20 agency had said that talc with asbestos 21 causes cancer. You asked him the 22 question. 23 MR. HEGARTY: I did not ask 24 him that question. I asked him if any</p>	<p style="text-align: right;">Page 537</p> <p>1 ERRATA SHEET 2 3 Page No.____Line No.____Change to:_____ 4 _____ 5 Page No.____Line No.____Change to:_____ 6 _____ 7 Page No.____Line No.____Change to:_____ 8 _____ 9 Page No.____Line No.____Change to:_____ 10 _____ 11 Page No.____Line No.____Change to:_____ 12 _____ 13 Page No.____Line No.____Change to:_____ 14 _____ 15 Page No.____Line No.____Change to:_____ 16 _____ 17 Page No.____Line No.____Change to:_____ 18 _____ 19 Page No.____Line No.____Change to:_____ 20 _____ 21 Page No.____Line No.____Change to:_____ 22 _____ 23 Page No.____Line No.____Change to:_____ 24 _____</p>



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## 1 DECLARATION UNDER PENALTY OF PERJURY

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I declare under penalty of  
perjury that I have read the entire transcript of  
my Deposition taken in the captioned matter  
or the same has been read to me, and  
the same is true and accurate, save and  
except for changes and/or corrections, if  
any, as indicated by me on the DEPOSITION  
ERRATA SHEET hereof, with the understanding  
that I offer these changes as if still under  
oath.

14

Signed on the \_\_\_\_\_ day of  
\_\_\_\_\_, 2024.

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\_\_\_\_\_  
BERNARD L. HARLOW, PHD

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## 1 CERTIFICATE OF REPORTER

2 DISTRICT OF COLUMBIA )

3

I, Denise Dobner Vickery, a  
Registered Court Reporter and Notary Public of  
the District of Columbia, do hereby certify that  
the witness was first duly sworn by me.

7

I do further certify that the  
foregoing is a verbatim transcript of the  
testimony as taken stenographically by me at the  
time, place and on the date herein set forth, to  
the best of my ability.

12

I do further certify that I am  
neither a relative nor employee nor counsel of  
any of the parties to this action, and that I am  
neither a relative nor employee of such counsel,  
and that I am not financially interested in the  
outcome of this action.

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*Denise D. Vickery*

DENISE DOBNER VICKERY, CRR,RMR  
Notary Public in and for the  
District of Columbia

My Commission expires: March 14, 2028

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.



VERITEXT LEGAL SOLUTIONS

COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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